



(12) **United States Patent**
Moisa et al.

(10) **Patent No.:** **US 9,452,016 B2**
(45) **Date of Patent:** **Sep. 27, 2016**

(54) **CATHETER SYSTEM**

(71) Applicant: **KARDIUM INC.**, Richmond (CA)

(72) Inventors: **Saar Moisa**, Vancouver (CA); **Marius J. Postma**, Coquitlam (CA)

(73) Assignee: **KARDIUM INC.**, Burnaby (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 185 days.

(21) Appl. No.: **14/136,946**

(22) Filed: **Dec. 20, 2013**

(65) **Prior Publication Data**

US 2014/0114307 A1 Apr. 24, 2014

Related U.S. Application Data

(63) Continuation-in-part of application No. 13/942,354, filed on Jul. 15, 2013, which is a continuation of application No. PCT/US2012/022061, filed on Jan. 20, 2012.

(Continued)

(51) **Int. Cl.**
A61B 18/14 (2006.01)
A61B 5/042 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 18/1492** (2013.01); **A61B 5/0422** (2013.01); **A61B 5/6858** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 1/0052; A61B 2017/00367;
A61B 2017/0046; A61B 2017/00464; A61B
2017/00469; A61B 5/6852; A61B 5/6853;
A61B 5/6856; A61B 5/6858; A61B 5/6859;
A61B 1/00085; A61B 2018/00267; A61B

2018/1475; A61M 2025/0096; A61M
25/0074; A61M 25/0082; A61M 25/1018
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,114,202 A 9/1978 Roy et al.
4,164,046 A 8/1979 Cooley

(Continued)

FOREIGN PATENT DOCUMENTS

CN 101797181 A 8/2010
EP 0723467 B1 7/1996

(Continued)

OTHER PUBLICATIONS

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Office Action mailed Aug. 5, 2015 for U.S. Appl. No. 13/785,910, 79 pages.

(Continued)

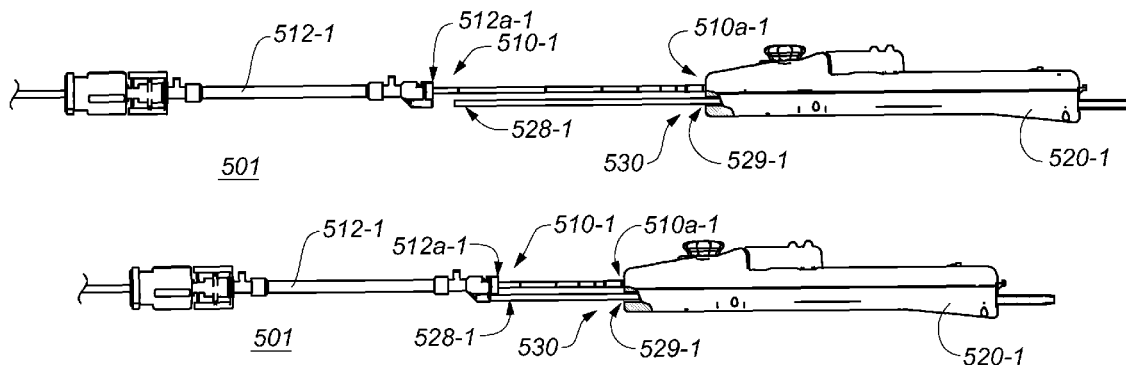
Primary Examiner — Jaymi Della

(74) *Attorney, Agent, or Firm* — Rossi, Kimms & McDowell LLP

(57) **ABSTRACT**

A manipulable portion of a catheter system advances out of a lumen of a catheter sheath at a distal end of a shaft, which is also within the lumen of the catheter sheath. The catheter system causes different advancement and retraction trajectories of a manipulable portion out of and into the lumen based at least upon different relative movements between the catheter sheath and the shaft. A projection and a corresponding receiver may be used to control relative positioning of the catheter sheath and the shaft, as well as to control positioning of the manipulable portion. The catheter system may control metering rates of a control element coupled to the manipulable portion during advancement and retraction of the manipulable portion. A control element of the catheter system has varying amounts of length outside a distal end of the catheter sheath during advancement and retraction of the manipulable portion.

36 Claims, 31 Drawing Sheets



Related U.S. Application Data		5,293,869	A *	3/1994	Edwards	A61B 5/042 600/375
(60)	Provisional application No. 61/435,213, filed on Jan. 21, 2011, provisional application No. 61/485,987, filed on May 13, 2011, provisional application No. 61/488,639, filed on May 20, 2011, provisional application No. 61/515,141, filed on Aug. 4, 2011.	5,312,435	A	5/1994	Nash et al.	
		5,317,952	A	6/1994	Immega	
		5,324,284	A	6/1994	Imran	
		5,327,889	A	7/1994	Imran	
		5,341,807	A	8/1994	Nardella	
		5,345,936	A	9/1994	Pomeranz et al.	
		5,351,679	A	10/1994	Mayzels et al.	
		5,366,443	A	11/1994	Eggers et al.	
		5,370,679	A	12/1994	Atlee, III	
(51)	Int. Cl.	5,379,773	A	1/1995	Hornsby	
	<i>A61B 5/00</i> (2006.01)	5,397,321	A	3/1995	Houser et al.	
	<i>A61B 5/026</i> (2006.01)	5,419,767	A	5/1995	Eggers et al.	
	<i>A61B 5/053</i> (2006.01)	5,450,860	A	9/1995	O'Connor	
	<i>A61B 5/06</i> (2006.01)	5,465,717	A	11/1995	Imran et al.	
	<i>A61M 25/00</i> (2006.01)	5,478,353	A	12/1995	Yoon	
	<i>A61B 18/00</i> (2006.01)	5,485,849	A	1/1996	Panescu et al.	
		5,496,267	A	3/1996	Drasler et al.	
(52)	U.S. Cl.	5,499,981	A	3/1996	Kordis	
	CPC <i>A61B 5/026</i> (2013.01); <i>A61B 5/0538</i>	5,531,760	A	7/1996	Alwafaie	
	(2013.01); <i>A61B 5/06</i> (2013.01); <i>A61B 5/6843</i>	5,545,193	A	8/1996	Fleischman et al.	
	(2013.01); <i>A61B 2018/0016</i> (2013.01); <i>A61B</i>	5,555,883	A	9/1996	Avitall	
	<i>2018/00166</i> (2013.01); <i>A61B 2018/00172</i>	5,557,967	A	9/1996	Renger	
	(2013.01); <i>A61B 2018/00184</i> (2013.01); <i>A61B</i>	5,575,810	A	11/1996	Swanson et al.	
	<i>2018/00267</i> (2013.01); <i>A61B 2018/00351</i>	5,593,424	A	1/1997	Northrup III	
	(2013.01); <i>A61B 2018/00357</i> (2013.01); <i>A61B</i>	5,598,848	A	2/1997	Swanson et al.	
	<i>2018/00577</i> (2013.01); <i>A61B 2018/00791</i>	5,599,345	A	2/1997	Edwards et al.	
	(2013.01); <i>A61B 2018/00839</i> (2013.01); <i>A61B</i>	5,620,481	A	4/1997	Desai et al.	
	<i>2018/00863</i> (2013.01); <i>A61B 2018/00875</i>	5,637,090	A	6/1997	McGee et al.	
	(2013.01); <i>A61B 2018/1475</i> (2013.01); <i>A61M</i>	5,662,587	A	9/1997	Grundfest et al.	
	<i>25/0074</i> (2013.01); <i>A61M 25/0082</i> (2013.01)	5,681,308	A	10/1997	Edwards et al.	
		5,681,336	A	10/1997	Clement et al.	
		5,687,723	A	11/1997	Avitall	
		5,687,737	A	11/1997	Branham et al.	
		5,697,285	A	12/1997	Nappi et al.	
(56)	References Cited	5,713,896	A	2/1998	Nardella	
	U.S. PATENT DOCUMENTS	5,713,942	A	2/1998	Stern et al.	
		5,716,397	A	2/1998	Myers	
		5,720,726	A	2/1998	Marcadis et al.	
		5,728,114	A	3/1998	Evans et al.	
		5,730,127	A	3/1998	Avitall	
		5,762,066	A	6/1998	Law et al.	
		5,769,846	A	6/1998	Edwards et al.	
		5,782,239	A	7/1998	Webster, Jr.	
		5,782,879	A	7/1998	Rosborough et al.	
		5,800,495	A	9/1998	Machek et al.	
		5,823,189	A	10/1998	Kordis	
		5,824,066	A	10/1998	Gross	
		5,836,947	A	11/1998	Fleischman et al.	
		5,836,990	A	11/1998	Li	
		5,853,422	A	12/1998	Huebsch et al.	
		5,868,755	A	2/1999	Kanner et al.	
		5,876,343	A	3/1999	Teo	
		5,881,727	A	3/1999	Edwards	
		5,885,278	A	3/1999	Fleischman	
		5,891,136	A	4/1999	McGee et al.	
		5,904,711	A	5/1999	Flom et al.	
		5,916,163	A	6/1999	Panescu et al.	
		5,919,207	A	7/1999	Taheri	
		5,921,924	A	7/1999	Avitall	
		5,935,075	A	8/1999	Casscells et al.	
		5,935,079	A	8/1999	Swanson et al.	
		5,941,251	A	8/1999	Panescu et al.	
		5,944,715	A	8/1999	Goble et al.	
		5,961,440	A	10/1999	Schweich, Jr. et al.	
		5,968,040	A	10/1999	Swanson et al.	
		5,984,950	A	11/1999	Cragg et al.	
		6,001,069	A	12/1999	Tachibana et al.	
		6,001,093	A	12/1999	Swanson et al.	
		6,014,581	A	1/2000	Whayne et al.	
		6,023,638	A	2/2000	Swanson	
		6,030,382	A	2/2000	Fleischman et al.	
		6,036,689	A	3/2000	Tu et al.	
		6,063,082	A	5/2000	DeVore et al.	
		6,071,282	A	6/2000	Fleischman	
		6,104,944	A	8/2000	Martinelli	
		6,106,522	A	8/2000	Fleischman et al.	
		6,123,702	A	9/2000	Swanson et al.	

(56)

References Cited

U.S. PATENT DOCUMENTS

6,138,043	A	10/2000	Avitall	6,989,010	B2	1/2006	Francischelli et al.
6,142,993	A	11/2000	Whayne et al.	6,989,028	B2	1/2006	Lashinski et al.
6,156,046	A	12/2000	Passafaro et al.	6,994,093	B2	2/2006	Murphy et al.
6,210,432	B1	4/2001	Solem et al.	6,997,951	B2	2/2006	Solem et al.
6,216,043	B1	4/2001	Swanson et al.	7,001,383	B2	2/2006	Keidar
6,217,573	B1	4/2001	Webster	7,025,776	B1	4/2006	Houser et al.
6,241,747	B1	6/2001	Ruff	7,048,734	B1	5/2006	Fleischman et al.
6,248,124	B1	6/2001	Pedros et al.	7,050,848	B2	5/2006	Hoey et al.
6,258,258	B1	7/2001	Sartori et al.	7,052,487	B2	5/2006	Cohn et al.
6,266,550	B1	7/2001	Selmon et al.	7,068,867	B2	6/2006	Adoram et al.
6,304,769	B1	10/2001	Arenson et al.	7,141,019	B2	11/2006	Pearlman
6,306,135	B1	10/2001	Ellman et al.	7,144,363	B2	12/2006	Pai et al.
6,308,091	B1	10/2001	Avitall	7,166,127	B2	1/2007	Spence et al.
6,319,249	B1	11/2001	Tollner	7,174,201	B2	2/2007	Govari et al.
6,322,559	B1	11/2001	Daulton et al.	7,177,677	B2	2/2007	Kaula et al.
6,330,478	B1*	12/2001	Lee A61N 1/06 606/41	7,186,210	B2	3/2007	Feld et al.
6,346,105	B1	2/2002	Tu et al.	7,187,964	B2	3/2007	Khoury
6,350,263	B1	2/2002	Wetzig et al.	7,189,202	B2	3/2007	Lau et al.
6,358,258	B1	3/2002	Arcia et al.	7,255,695	B2	8/2007	Falwell et al.
6,383,151	B1	5/2002	Diederich et al.	7,276,044	B2	10/2007	Ferry et al.
6,389,311	B1	5/2002	Whayne et al.	7,279,007	B2	10/2007	Nikolic et al.
6,391,024	B1	5/2002	Sun et al.	7,300,435	B2	11/2007	Wham et al.
6,391,048	B1	5/2002	Ginn et al.	7,303,526	B2	12/2007	Sharkey et al.
6,391,054	B2	5/2002	Carpentier et al.	7,335,196	B2	2/2008	Swanson et al.
6,402,781	B1	6/2002	Langberg et al.	7,481,808	B2	1/2009	Koyfman et al.
6,436,052	B1	8/2002	Nikolic et al.	7,507,252	B2	3/2009	Lashinski et al.
6,475,223	B1	11/2002	Werp et al.	7,530,980	B2	5/2009	Hooven
6,485,409	B1	11/2002	Voloshin et al.	7,736,388	B2	6/2010	Goldfarb et al.
6,485,482	B1	11/2002	Belef	7,738,967	B2	6/2010	Salo
6,485,489	B2	11/2002	Teirstein et al.	8,103,338	B2	1/2012	Harlev et al.
6,506,210	B1	1/2003	Kanner	D654,588	S	2/2012	Taube et al.
6,514,249	B1	2/2003	Maguire et al.	8,118,853	B2	2/2012	Grewe
6,529,756	B1	3/2003	Phan et al.	8,150,499	B2	4/2012	Gelbart et al.
6,537,198	B1	3/2003	Vidlund et al.	D660,967	S	5/2012	Braido et al.
6,537,314	B2	3/2003	Langberg et al.	8,224,432	B2	7/2012	Macadam et al.
6,540,670	B1	4/2003	Hirata et al.	D717,954	S	11/2014	Hjelle et al.
6,551,310	B1	4/2003	Ganz et al.	9,198,713	B2	12/2015	Wallace et al.
6,551,312	B2	4/2003	Zhang et al.	2001/0003158	A1	6/2001	Kensley et al.
6,569,160	B1	5/2003	Goldin et al.	2001/0005787	A1	6/2001	Oz et al.
6,569,198	B1	5/2003	Wilson et al.	2001/0018611	A1	8/2001	Solem et al.
6,575,971	B2	6/2003	Hauck et al.	2001/0020126	A1	9/2001	Swanson et al.
6,589,208	B2	7/2003	Ewers et al.	2001/0021867	A1	9/2001	Kordis et al.
6,616,684	B1	9/2003	Vidlund et al.	2002/0002329	A1	1/2002	Avitall
6,626,930	B1	9/2003	Allen et al.	2002/0016628	A1	2/2002	Langberg et al.
6,632,238	B2	10/2003	Ginn et al.	2002/0087156	A1	7/2002	Maguire et al.
6,635,056	B2	10/2003	Kadhiresan et al.	2002/0087173	A1	7/2002	Alferness et al.
6,640,119	B1	10/2003	Budd et al.	2002/0099415	A1	7/2002	Panescu et al.
6,662,034	B2	12/2003	Segner et al.	2002/0107478	A1	8/2002	Wendlandt
D484,979	S	1/2004	Fontaine	2002/0107511	A1	8/2002	Collins et al.
6,704,590	B2	3/2004	Haldeman	2002/0107530	A1	8/2002	Saucer et al.
6,723,038	B1	4/2004	Schroeder et al.	2002/0115941	A1	8/2002	Whayne et al.
6,726,716	B2	4/2004	Marquez	2002/0115944	A1	8/2002	Mendes et al.
6,760,616	B2	7/2004	Hoey et al.	2002/0169504	A1	11/2002	Alferness et al.
6,780,197	B2	8/2004	Roe et al.	2002/0177782	A1	11/2002	Penner
6,788,969	B2	9/2004	Dupree et al.	2002/0183836	A1	12/2002	Liddicoat et al.
6,797,001	B2	9/2004	Mathis et al.	2002/0183841	A1	12/2002	Cohn et al.
6,800,090	B2	10/2004	Alferness et al.	2002/0188170	A1	12/2002	Santamore et al.
6,824,562	B2	11/2004	Mathis et al.	2003/0028118	A1	2/2003	Dupree et al.
6,837,886	B2	1/2005	Collins et al.	2003/0028183	A1	2/2003	Sanchez et al.
6,852,076	B2	2/2005	Nikolic et al.	2003/0050685	A1	3/2003	Nikolic et al.
6,855,143	B2	2/2005	Davison et al.	2003/0055420	A1	3/2003	Kadhiresan et al.
6,890,353	B2	5/2005	Cohn et al.	2003/0069570	A1	4/2003	Witzel et al.
6,892,091	B1	5/2005	Ben-Haim et al.	2003/0069636	A1	4/2003	Solem et al.
6,899,674	B2	5/2005	Viebach et al.	2003/0078465	A1	4/2003	Pai et al.
6,907,297	B2	6/2005	Wellman et al.	2003/0078671	A1	4/2003	Lesniak et al.
6,908,478	B2	6/2005	Alferness et al.	2003/0105384	A1	6/2003	Sharkey et al.
6,913,576	B2	7/2005	Bowman	2003/0105520	A1	6/2003	Alferness et al.
6,918,903	B2	7/2005	Bass	2003/0109770	A1	6/2003	Sharkey et al.
6,926,669	B1	8/2005	Stewart et al.	2003/0176810	A1	9/2003	Maahs et al.
6,942,657	B2	9/2005	Sinofsky et al.	2003/0181819	A1	9/2003	Desai
6,949,122	B2	9/2005	Adams et al.	2003/0229395	A1	12/2003	Cox
6,960,206	B2	11/2005	Keane	2004/0002626	A1	1/2004	Feld et al.
6,960,229	B2	11/2005	Mathis et al.	2004/0054279	A1	3/2004	Hanley
6,986,775	B2	1/2006	Morales et al.	2004/0133220	A1	7/2004	Lashinski et al.
				2004/0133273	A1	7/2004	Cox
				2004/0138744	A1	7/2004	Lashinski et al.
				2004/0153146	A1	8/2004	Lashinski et al.
				2004/0158321	A1	8/2004	Reuter et al.
				2004/0176797	A1	9/2004	Opolski

(56)

References Cited

U.S. PATENT DOCUMENTS

2004/0181139	A1	9/2004	Falwell et al.
2004/0186566	A1	9/2004	Hindrichs et al.
2004/0215232	A1	10/2004	Belhe et al.
2004/0243170	A1	12/2004	Suresh et al.
2004/0249408	A1	12/2004	Murphy et al.
2004/0249453	A1	12/2004	Cartledge et al.
2004/0267358	A1	12/2004	Reitan
2005/0004668	A1	1/2005	Aklog et al.
2005/0015109	A1	1/2005	Lichtenstein
2005/0054938	A1	3/2005	Wehman et al.
2005/0055089	A1	3/2005	Macoviak et al.
2005/0060030	A1	3/2005	Lashinski et al.
2005/0064665	A1	3/2005	Han
2005/0065420	A1	3/2005	Collins et al.
2005/0065504	A1	3/2005	Melsky et al.
2005/0080402	A1	4/2005	Santamore et al.
2005/0096047	A1	5/2005	Haberman et al.
2005/0096647	A1	5/2005	Steinke et al.
2005/0107723	A1	5/2005	Wehman et al.
2005/0107871	A1	5/2005	Realyvasquez et al.
2005/0125030	A1	6/2005	Forsberg et al.
2005/0148892	A1	7/2005	Desai
2005/0149014	A1	7/2005	Hauck et al.
2005/0149159	A1	7/2005	Andreas et al.
2005/0154252	A1	7/2005	Sharkey et al.
2005/0182365	A1	8/2005	Hennemann et al.
2005/0187620	A1	8/2005	Pai et al.
2005/0197593	A1	9/2005	Burbank et al.
2005/0197692	A1	9/2005	Pai et al.
2005/0197693	A1	9/2005	Pai et al.
2005/0197694	A1	9/2005	Pai et al.
2005/0203558	A1	9/2005	Maschke
2005/0209636	A1	9/2005	Widomski et al.
2005/0216054	A1	9/2005	Widomski et al.
2005/0240249	A1	10/2005	Tu et al.
2005/0251116	A1	11/2005	Steinke et al.
2005/0251132	A1	11/2005	Oral et al.
2005/0256521	A1	11/2005	Kozel
2005/0261580	A1	11/2005	Willis et al.
2005/0267458	A1	12/2005	Paul et al.
2005/0267574	A1	12/2005	Cohn et al.
2006/0009755	A1	1/2006	Sra
2006/0009756	A1	1/2006	Francischelli et al.
2006/0014998	A1	1/2006	Sharkey et al.
2006/0015002	A1	1/2006	Moaddeb et al.
2006/0015003	A1	1/2006	Moaddes et al.
2006/0015038	A1	1/2006	Weymarn-Scharli
2006/0015096	A1	1/2006	Hauck et al.
2006/0025800	A1	2/2006	Suresh
2006/0030881	A1	2/2006	Sharkey et al.
2006/0085049	A1	4/2006	Cory et al.
2006/0089637	A1	4/2006	Werneth et al.
2006/0100618	A1	5/2006	Chan et al.
2006/0106298	A1	5/2006	Ahmed et al.
2006/0135968	A1	6/2006	Schaller
2006/0135970	A1	6/2006	Schaller
2006/0184242	A1	8/2006	Lichtenstein
2006/0199995	A1	9/2006	Vijay
2006/0229491	A1	10/2006	Sharkey et al.
2006/0235286	A1	10/2006	Stone et al.
2006/0235314	A1	10/2006	Migliuolo et al.
2006/0264980	A1	11/2006	Khairkhahan et al.
2006/0281965	A1	12/2006	Khairkhahan et al.
2006/0293698	A1	12/2006	Douk
2006/0293725	A1	12/2006	Rubinsky et al.
2007/0016068	A1	1/2007	Grunwald et al.
2007/0027533	A1	2/2007	Douk
2007/0038208	A1	2/2007	Kefer
2007/0083193	A1	4/2007	Werneth et al.
2007/0083195	A1	4/2007	Werneth et al.
2007/0088362	A1	4/2007	Bonutti et al.
2007/0115390	A1	5/2007	Makara et al.
2007/0118215	A1	5/2007	Moaddeb
2007/0129717	A1	6/2007	Brown, III et al.
2007/0161846	A1	7/2007	Nikolic et al.
2007/0198058	A1	8/2007	Gelbart et al.
2007/0213578	A1	9/2007	Khairkhahan et al.
2007/0213815	A1	9/2007	Khairkhahan et al.
2007/0232858	A1	10/2007	MacNamara et al.
2007/0249999	A1	10/2007	Sklar et al.
2007/0270688	A1	11/2007	Gelbart et al.
2007/0299343	A1	12/2007	Waters
2008/0004534	A1	1/2008	Gelbart et al.
2008/0004643	A1	1/2008	To et al.
2008/0004697	A1	1/2008	Lichtenstein et al.
2008/0045778	A1	2/2008	Lichtenstein et al.
2008/0071298	A1	3/2008	Khairkhahan et al.
2008/0262337	A1	10/2008	Falwell et al.
2008/0281322	A1	11/2008	Sherman et al.
2008/0312713	A1	12/2008	Wilfley et al.
2009/0018617	A1	1/2009	Skelton et al.
2009/0024138	A1	1/2009	Saleh
2009/0069704	A1	3/2009	MacAdam et al.
2009/0131930	A1	5/2009	Gelbart et al.
2009/0157058	A1	6/2009	Ferren et al.
2009/0171274	A1	7/2009	Harlev et al.
2009/0192441	A1	7/2009	Gelbart et al.
2009/0270737	A1	10/2009	Thornton
2009/0287271	A1	11/2009	Blum et al.
2009/0287304	A1	11/2009	Dahlgren et al.
2010/0121147	A1	5/2010	Oskin et al.
2010/0211052	A1	8/2010	Brown et al.
2010/0249771	A1	9/2010	Pearson et al.
2010/0268059	A1	10/2010	Ryu et al.
2011/0125172	A1	5/2011	Gelbart et al.
2011/0172658	A1	7/2011	Gelbart et al.
2011/0282491	A1	11/2011	Prisco et al.
2012/0158016	A1	6/2012	Gelbart et al.
2012/0165829	A1	6/2012	Chen et al.
2012/0271135	A1	10/2012	Burke et al.
2013/0165916	A1	6/2013	Mathur et al.
2013/0172883	A1	7/2013	Lopes et al.
2013/0178850	A1	7/2013	Lopes et al.
2013/0178851	A1	7/2013	Lopes et al.
2013/0184705	A1	7/2013	Gelbart et al.
2013/0184706	A1	7/2013	Gelbart et al.
2013/0190587	A1	7/2013	Lopes et al.
2013/0197513	A1	8/2013	Lopes et al.
2013/0241929	A1	9/2013	Massarwa et al.
2013/0304065	A1	11/2013	Lopes et al.
2013/0310828	A1	11/2013	Reinders et al.
2014/0350552	A1	11/2014	Highsmith
2015/0126993	A1	5/2015	Gelbart et al.
2015/0157400	A1	6/2015	Gelbart et al.

FOREIGN PATENT DOCUMENTS

WO	9510320	A1	4/1995
WO	95/20349	A1	8/1995
WO	97/17892	A1	5/1997
WO	0108575	A2	2/2001
WO	02/087437	A1	11/2002
WO	03015611	A2	2/2003
WO	03077800	A1	9/2003
WO	2004012629	A1	2/2004
WO	2004047679	A1	6/2004
WO	2004084746	A2	10/2004
WO	2004100803	A1	11/2004
WO	2005070330	A1	8/2005
WO	2005102181	A1	11/2005
WO	2006017809	A2	2/2006
WO	2006105121	A2	10/2006
WO	2006135747	A2	12/2006
WO	2006135749	A2	12/2006
WO	2007021647	A2	2/2007
WO	2007115390	A1	10/2007
WO	2008002606	A2	1/2008
WO	2009011721	A1	1/2009
WO	2009065042	A2	5/2009

(56)

References Cited

FOREIGN PATENT DOCUMENTS

WO 2012/100184 A2 7/2012
 WO 2012/100185 A2 7/2012
 WO 2013/173917 A1 11/2013

OTHER PUBLICATIONS

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Office Action mailed May 22, 2015 for U.S. Appl. No. 13/782,889, 86 pages.

Non-final Office Action in co-pending U.S. Appl. No. 13/782,867, dated Apr. 15, 2015.

Non-final Office Action issued in co-pending U.S. Appl. No. 13/782,903, dated Apr. 28, 2015.

International Search Report mailed Mar. 10, 2015, for International Application PCT/CA2014/051144; 10 pages.

Written Opinion mailed Mar. 10, 2015, for International Application PCT/CA2014/051144; 4 pages.

Biotronik's "AlCath Flutter Gold Cath for Atrial Flutter Available in EU", Sep. 19, 2013, medGadget, 3 pgs, <http://www.medgadget.com/2013/09/biotroniks-alcath-flutter-gold-cath-for-atrial-flutter-unveiled-in-europe.html> [Jun. 24, 2014 2:37:09 PM].

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Notice of Allowance dated Oct. 23, 2014 for U.S. Appl. No. 11/475,950, 10 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Supplemental Notice of Allowance dated Oct. 6, 2014 for U.S. Appl. No. 11/941,819, 4 pgs.

Gelbart et al., Medical Device for Use in Bodily Lumens, for Example an Atrium, Amendment filed Sep. 22, 2014, for co-pending U.S. Appl. No. 13/070,215, 18 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Notice of Allowance mailed Nov. 13, 2014 for U.S. Appl. No. 13/070,215, 54 pages.

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Amendment filed Apr. 10, 2014; Supplemental Amendment filed Feb. 12, 2013 for co-pending U.S. Appl. No. 11/475,950, 21 pgs.

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Preliminary Amendment filed Aug. 22, 2014; Preliminary Amendment filed Mar. 5, 2013 for co-pending U.S. Appl. No. 13/785,910, 10 pgs.

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Preliminary Amendment filed Aug. 22, 2014; Preliminary Amendment filed Mar. 5, 2013 for co-pending U.S. Appl. No. 13/785,931, 10 pgs.

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Preliminary Amendment filed Oct. 22, 2013 for co-pending U.S. Appl. No. 13/942,354, 13 pgs.

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Preliminary Amendment filed Aug. 20, 2014 for co-pending U.S. Appl. No. 13/782,889, 11 pgs.

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Preliminary Amendment filed Mar. 14, 2013 for co-pending U.S. Appl. No. 13/782,867, 8 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Amendment filed Jul. 3, 2014; Amendment filed Apr. 2, 2012; Amendment filed Mar. 1, 2012; Amendment filed Nov. 23, 2011; Replacement drawings filed Feb. 13, 2008 for U.S. Appl. No. 11/941,819, 155 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Preliminary Amendment filed May 12, 2014; Preliminary Amendment filed May 2, 2014 for U.S. Appl. No. 14/229,305, 12 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Preliminary Amendment filed May 12, 2014; Preliminary Amendment filed May 2, 2014 for U.S. Appl. No. 14/229,250, 10 pgs.

Gelbart et al., "Apparatus and Method for Intra-Cardiac Mapping and Ablation", Office Action dated Dec. 13, 2013; Notice of Allowance dated Jul. 25, 2014 for co-pending U.S. Appl. No. 11/475,950, 19 pgs.

Gelbart et al., "Medical Device for Use in Bodily Lumens, for Example an Atrium", Office Action dated Jan. 3, 2012; Office Action dated Apr. 3, 2014; Notice of Allowance dated Aug. 26, 2014 for co-pending U.S. Appl. No. 11/941,819, 35 pgs.

Gelbart et al., Medical Device for Use in Bodily Lumens, for Example an Atrium, Office Action dated Jun. 20, 2014, for co-pending U.S. Appl. No. 13/070,215, 8 pgs.

Becker R. et al., "Ablation of Atrial Fibrillation: Energy Sources and Navigation Tools: A Review", Journal of Electrophysiology, 37 (Supplement 2004): 55-62, 2004.

Calkins, Hugh, "Electrophysiology: Radiofrequency Catheter Ablation of Supraventricular Arrhythmias", Heart, 85:594-600, 2001.

De Ponti et al., "Non-Fluoroscopic Mapping Systems for Electrophysiology: The 'Tool or Toy' Dilemma After 10 Years", European Heart Journal 27:1134-1136, 2006.

Bard, "Mesh Ablator Catheter", Brochure, 2008, 4 pgs, Bard Electrophysiology Division, C.R. Bard Inc., 55 Technology Drive Lowell, MA 07851 USA.

Biotronik's "AlCath Flutter Gold Cath for Atrial Flutter Available in EU", medGadget, 3 pgs, <http://www.medgadget.com/2013/09/biotroniks-alcath-flutter-gold-cath-for-atrial-flutter-unveiled-in-europe.html> [Jun. 24, 2014 2:37:09 PM].

"Constellation Mapping Catheters", Brochure, Boston Scientific Corp., 2 pgs © 2007 Boston Scientific Corporation.

"Waveforms and Segments", Ensite System Instructions for use, 54-06154-001 Rev02, Chapter 7 pp. 85-90 © 2007 St. Jude Medical.

"ThermoCool® Irrigated Tip Catheter", Brochure, Biosense Webster, 4 pgs, Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765, USA, © Biosense Webster, Inc. 2009 All rights reserved. 1109003.0.

Gelbart "Medical Device for Use in Bodily Lumens, for Example an Atrium", OA mailed Jul. 25, 2011 for U.S. Appl. No. 11/941,819, now published as US 2009-0131930 A1.

Extended European Search Report mailed Aug. 20, 2013 issued in EP Patent Application No. 13172848.7.

Written Opinion dated Aug. 22, 2012 for PCT/US2012/022061, 6 pgs.

International Search Report and Written Opinion mailed Aug. 2, 2013 issued in PCT/CA2013/050350.

International Search Report and Written Opinion mailed Sep. 17, 2013 issued in PCT/US2013/039982.

International Search Report and Written Opinion mailed Sep. 27, 2013 issued in PCT/US2013/039977.

International Search Report dated Jul. 30, 2012 for PCT/US2012/022062, 5 pgs.

Written Opinion dated Jul. 30, 2012 for PCT/US2012/022062, 5 pgs.

International Search Report dated Aug. 22, 2012 for PCT/US2012/022061, 5 pgs.

"Phased RF Catheter Ablation System", 2014 Medtronic Inc., 2 pgs, <http://www.medtronic.eu/your-health/atrial-fibrillation/about-the-therapy/our-phased-rf-ablation-system/> [Jun. 24, 2014 2:38:05 PM].

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Amendment filed Aug. 24, 2015 for U.S. Appl. No. 13/782,889, 21 pages.

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Amendment filed Aug. 28, 2015 for U.S. Appl. No. 13/782,903, 19 pages.

Lopes et al., "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Amendment filed Sep. 14, 2015 for U.S. Appl. No. 13/782,867, 25 pages.

Lopes et al., "High-Density Electrode-Based Medical Device System", Amendment filed Oct. 9, 2015 for U.S. Appl. No. 13/793,213, 26 pages.

Lopes et al., "High-Density Electrode-Based Medical Device System", Amendment filed Oct. 9, 2015 for U.S. Appl. No. 13/793,076, 14 pages.

(56)

References Cited**OTHER PUBLICATIONS**

Examination Report issued in EP13172848.7, mailed Sep. 21, 2015.
 Extended European Search Report for corresponding EP 12736677.1, mail date Mar. 28, 2014.
 Extended European Search Report for corresponding EP 12736962.7, mail date Mar. 28, 2014.
 Office Action issued in U.S. Appl. No. 13/782,889, mailed Dec. 18, 2015.
 Office Action issued in U.S. Appl. No. 13/782,903, mailed Dec. 18, 2015.
 Extended European Search Report issued in EP15188407.9, mailed Jan. 21, 2016.
 Lopes et al. "Enhanced Medical Device for Use in Bodily Cavities, for Example an Atrium", Office Action mailed Jan. 25, 2016 for U.S. Appl. No. 13/782,867, 49 pages.
 Notice of Allowance issued in U.S. Appl. No. 13/793,076, dated Feb. 10, 2016.
 Final Office Action issued in U.S. Appl. No. 13/793,213, dated Feb. 26, 2016.
 Non-Final Office Action issued in U.S. Appl. No. 29/509,719, dated Feb. 25, 2016.
 Quayle issued in U.S. Appl. No. 29/509,621, dated Feb. 26, 2016.
 Quayle issued in U.S. Appl. No. 29/509,636, dated Feb. 26, 2016.
 Non-Final Office Action issued in U.S. Appl. No. 13/785,910 mailed Apr. 8, 2016.
 Lopes et al., "High-Density Electrode-Based Medical Device System", Office Action mailed Jul. 10, 2015 for U.S. Appl. No. 13/793,076, 98 pages.
 Lopes et al., "High-Density Electrode-Based Medical Device System", Office Action mailed Jul. 9, 2015 for U.S. Appl. No. 13/793,213, 99 pages.
 Extended European Search Report issued in EP13793216.6, mailed Oct. 30, 2015.
 Buchbinder, Maurice MD, "Dynamic Mitral Valve Annuloplasty: A Reshapable Ring for Residual and Recurring MR," from the Foundation for Cardiovascular Medicine, La Jolla, CA. May 24, 2007.
 Gabriel et al., "The Dielectric Properties of Biological Tissues: I. Literature Survey," *Phys. Med. Biol.* 41:2231-2249, 1996.
 Konings et al., "Development of an Intravascular Impedance Catheter for Detection of Fatty Lesions in Arteries," *IEEE Transactions on Medical Imaging*, 16(4):439-446, 1997.
 Mack, "New Techniques for Percutaneous Repair of the Mitral Valve," *Heart Failure Review*, 11:259-268, 2006.
 Otasevic et al., "First-in-Man Implantation of Left Ventricular Partitioning Device in a Patient With Chronic Heart Failure: Twelve-Month Follow-up," *Journal of Cardiac Failure* 13(7):517-520, 2007.
 Sharkey et al., "Left Ventricular Apex Occluder. Description of a Ventricular Partitioning Device," *EuroIntervention* 2:125-127, 2006.
 Stiles, et al., "Simulated Characterization of Atherosclerotic Lesions in the Coronary Arteries by Measurement of Bioimpedance," *IEE Transactions on Biomedical Engineering*, 50(7):916-921, 2003.
 Tanaka et al., "Artificial SMA Valve for Treatment of Urinary Incontinence: Upgrading of Valve and Introduction of Transcatheterous Transformer," *Bio-Medical Materials and Engineering* 9:97-112, 1999.
 Timek et al., "Septal-Lateral Annular Cinching ('SLAC') Reduces Mitral Annular Size Without Perturbing Normal Annular Dynamics," *Journal of Heart Valve Disease* 11 (1):2-10, 2002.
 Timek et al., "Septal-Lateral Annular Cinching Abolishes Acute Ischemic Mitral Regurgitation," *Journal of Thoracic and Cardiovascular Surgery*, 123(5):881-888, 2002.

Valvano et al., "Thermal Conductivity and Diffusivity of Biomaterials Measured with Self-Heated Thermistors," *International Journal of Thermodynamics*, 6(3):301-311, 1985.
 Gelbart et al., "Automatic Atherectomy System," Office Action mailed Mar. 4, 2009 for U.S. Appl. No. 11/436,584, 6 pages.
 Gelbart et al., "Automatic Atherectomy System," Amendment filed Aug. 4, 2009 for U.S. Appl. No. 11/436,584, 35 pages.
 Gelbart et al., "Automatic Atherectomy System," Office Action mailed Dec. 1, 2009 for U.S. Appl. No. 11/436,584, 8 pages.
 Gelbart et al., "Automatic Atherectomy System," Amendment filed Mar. 30, 2010 for U.S. Appl. No. 11/436,584, 20 pages.
 Gelbart et al., "Automatic Atherectomy System," Amendment filed Oct. 25, 2010 for U.S. Appl. No. 11/436,584, 9 pages.
 Gelbart et al., "Automatic Atherectomy System," Office Action mailed Dec. 14, 2010 for U.S. Appl. No. 11/436,584, 12 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Preliminary Amendment filed Aug. 29, 2007 for U.S. Appl. No. 11/475,950, 42 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Amendment filed Mar. 5, 2008 for U.S. Appl. No. 11/475,950, 11 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Office Action mailed Jun. 23, 2010 for U.S. Appl. No. 11/475,950, 18 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Amendment filed Aug. 16, 2010 for U.S. Appl. No. 11/475,950, 22 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Office Action mailed Nov. 23, 2010 for U.S. Appl. No. 11/475,950, 25 pages.
 Gelbart et al., "Intra-Cardiac Mapping and Ablation Method," Amendment filed Feb. 23, 2011 for U.S. Appl. No. 11/475,950, 28 pages.
 Gelbart et al., "Automatic Atherectomy System," Office Action mailed Jun. 15, 2011, for U.S. Appl. No. 12/950,871, 16 pages.
 Gelbart et al., "Liposuction System," Office Action mailed Mar. 16, 2011 for U.S. Appl. No. 12/010,458, 12 pages.
 Gelbart et al., "Liposuction System," Amendment filed Jun. 10, 2011 for U.S. Appl. No. 12/010,458, 10 pages.
 Lichtenstein "Method and Apparatus for Percutaneous Reduction of Anterior-Posterior Diameter of Mitral Valve," U.S. Appl. No. 10/690,131, filed Oct. 20, 2003, 31 pages.
 International Search Report, mailed Dec. 5, 2007, for PCT/US2007/014902, 4 pages.
 International Preliminary Report on Patentability, issued Jan. 6, 2009, for PCT/US2007/1014902, 8 pages.
 International Search Report, mailed Dec. 2, 2009, for PCT/US2008/083644, 4 pages.
 Written Opinion, mailed Dec. 5, 2007, for PCT/US2007/014902, 7 pages.
 Written Opinion, mailed Dec. 2, 2009, for PCT/US2008/083644, 9 pages.
 Gelbart et al., "Automatic Atherectomy System," Amendment filed Sep. 15, 2011 for U.S. Appl. No. 12/950,871, 21 pages.
 Gelbart et al., "Liposuction System," Amendment filed Dec. 7, 2011 for U.S. Appl. No. 12/010,458, 15 pages.
 Gelbart et al., "Liposuction System," Office Action mailed Sep. 14, 2011 for U.S. Appl. No. 12/010,458, 9 pages.
 Non-Final Office Action issued in U.S. Appl. No. 14/229,250 mailed Apr. 28, 2016.
 Non-Final Office Action issued in U.S. Appl. No. 14/229,305 mailed Apr. 29, 2016.

* cited by examiner

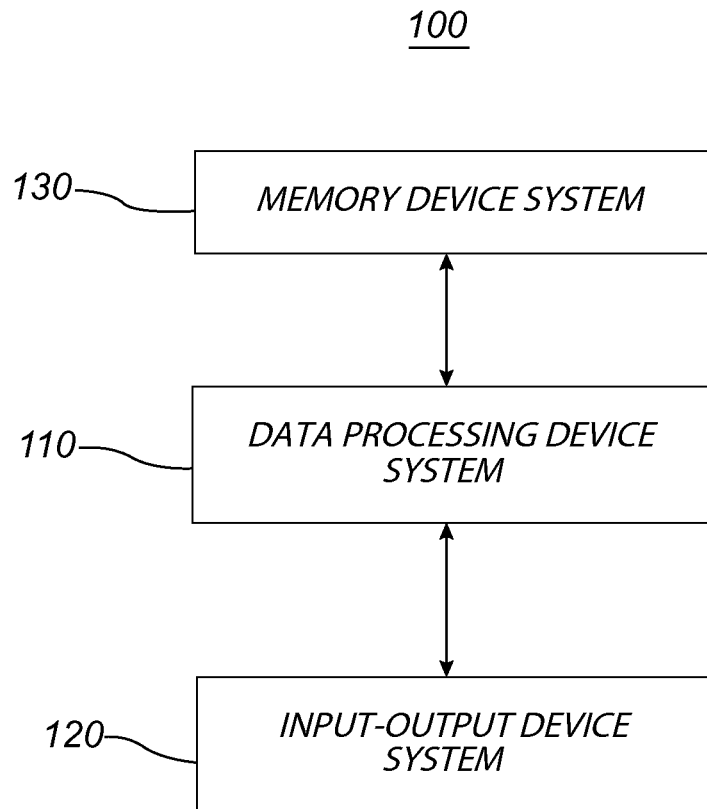


FIG. 1

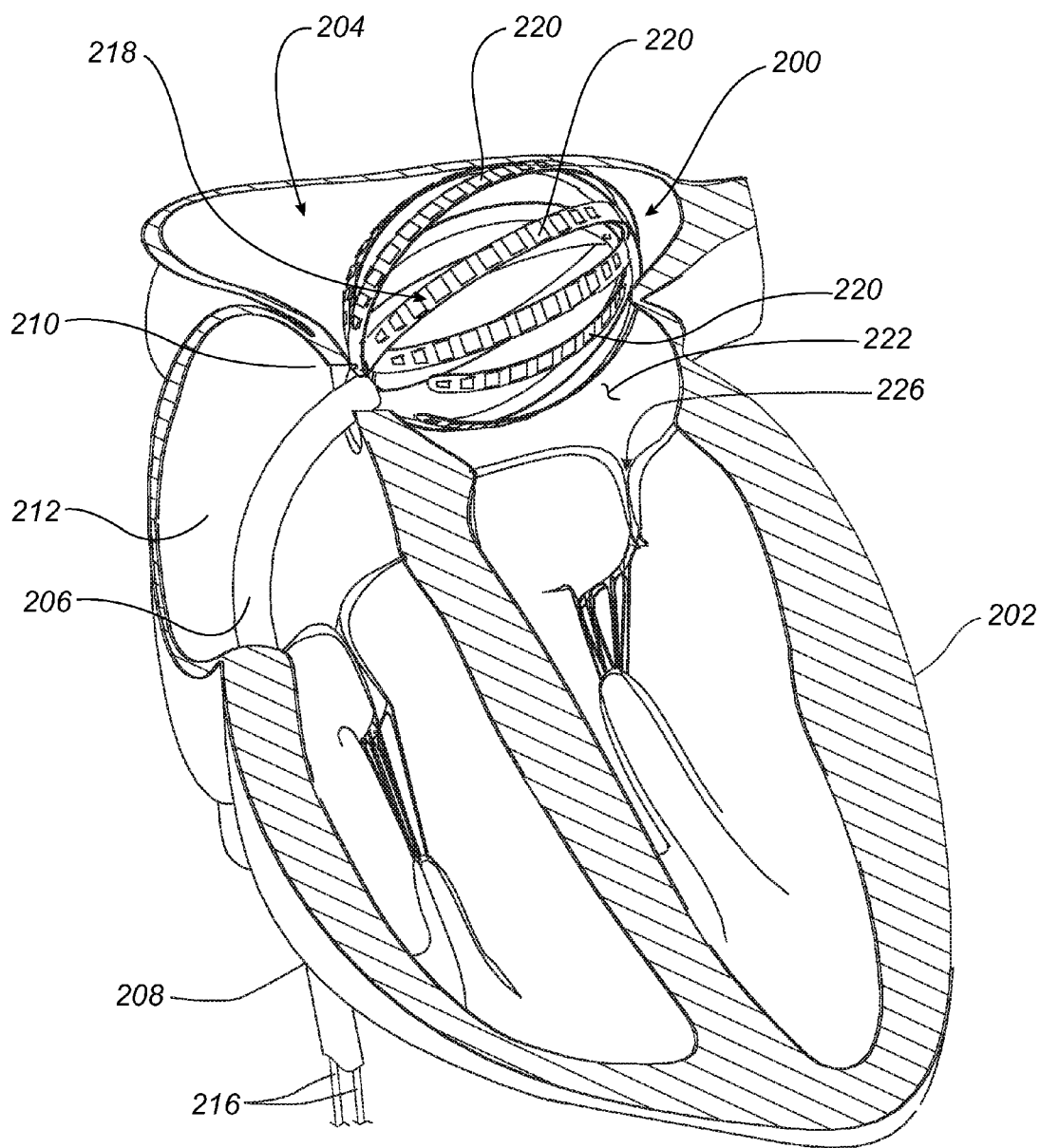
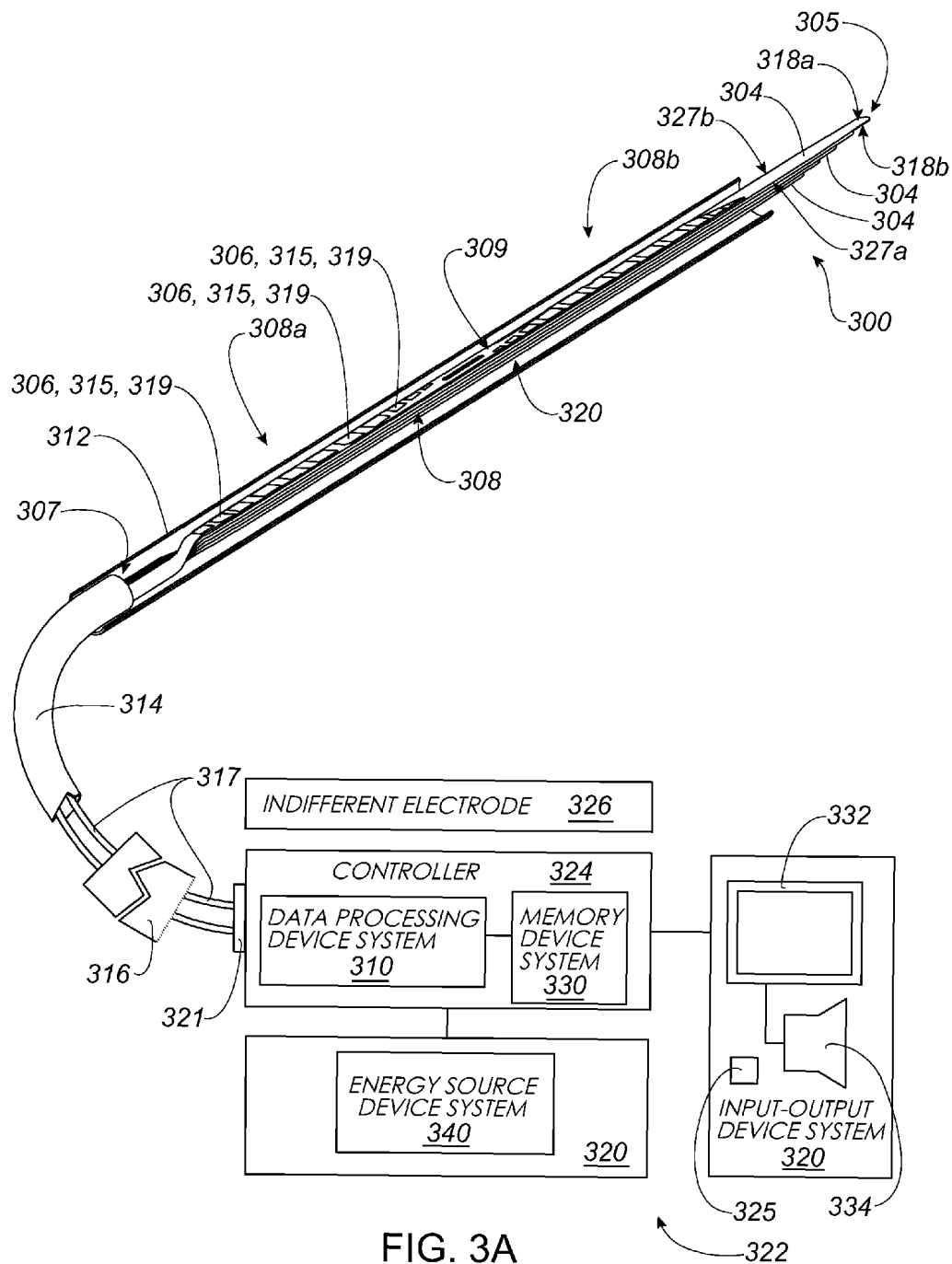


FIG. 2



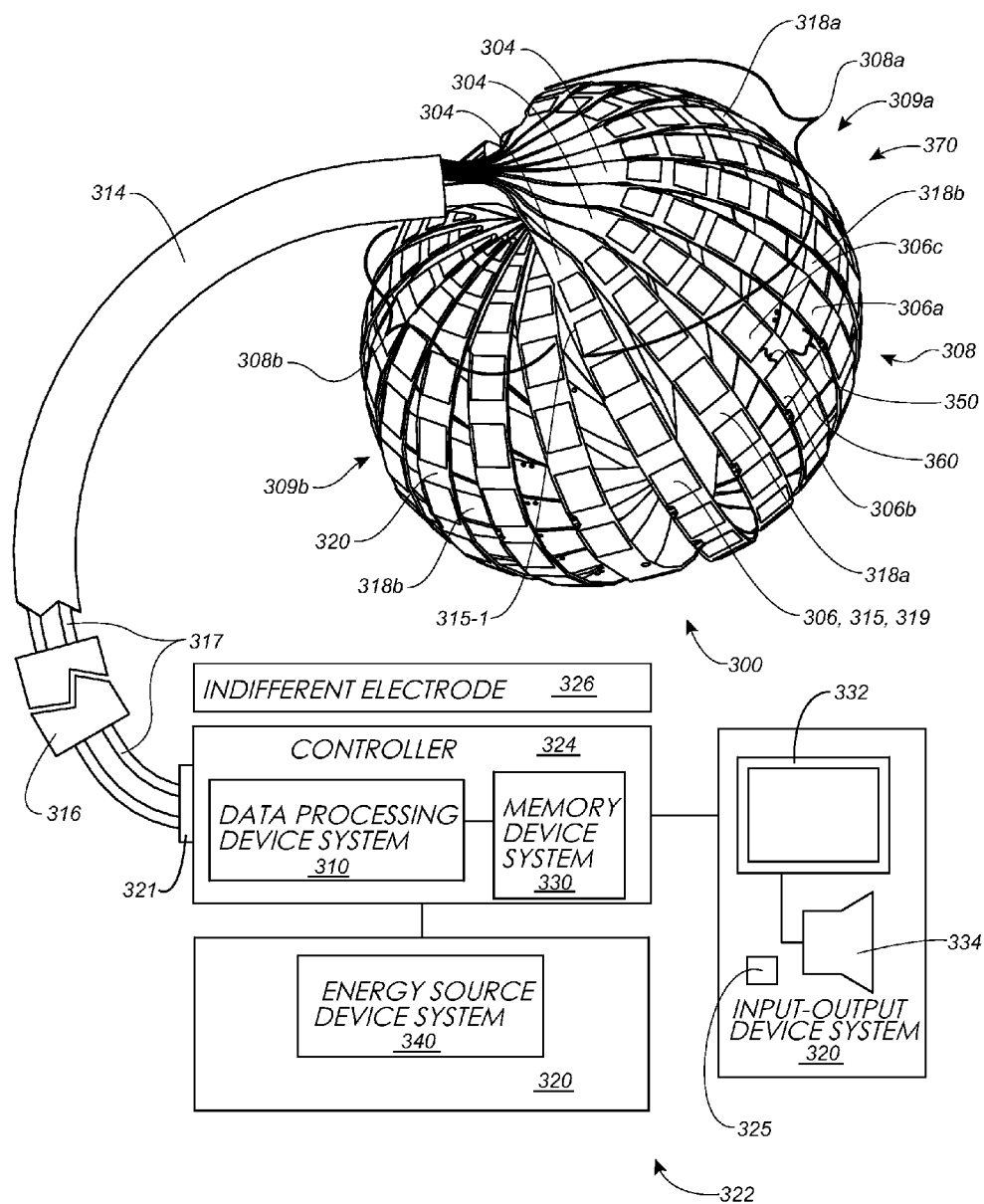


FIG. 3B

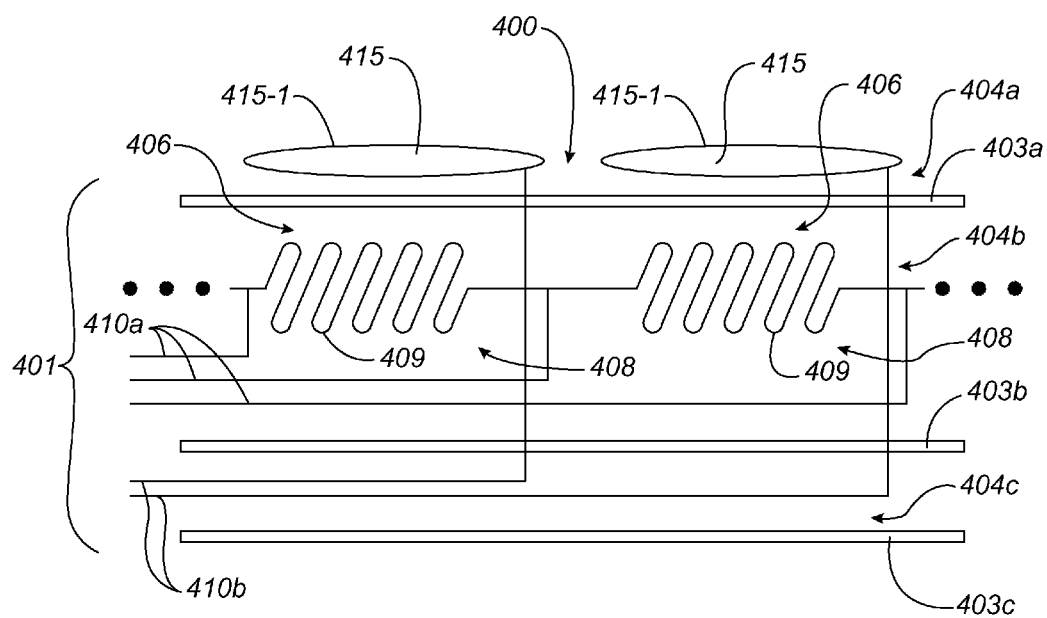


FIG. 4

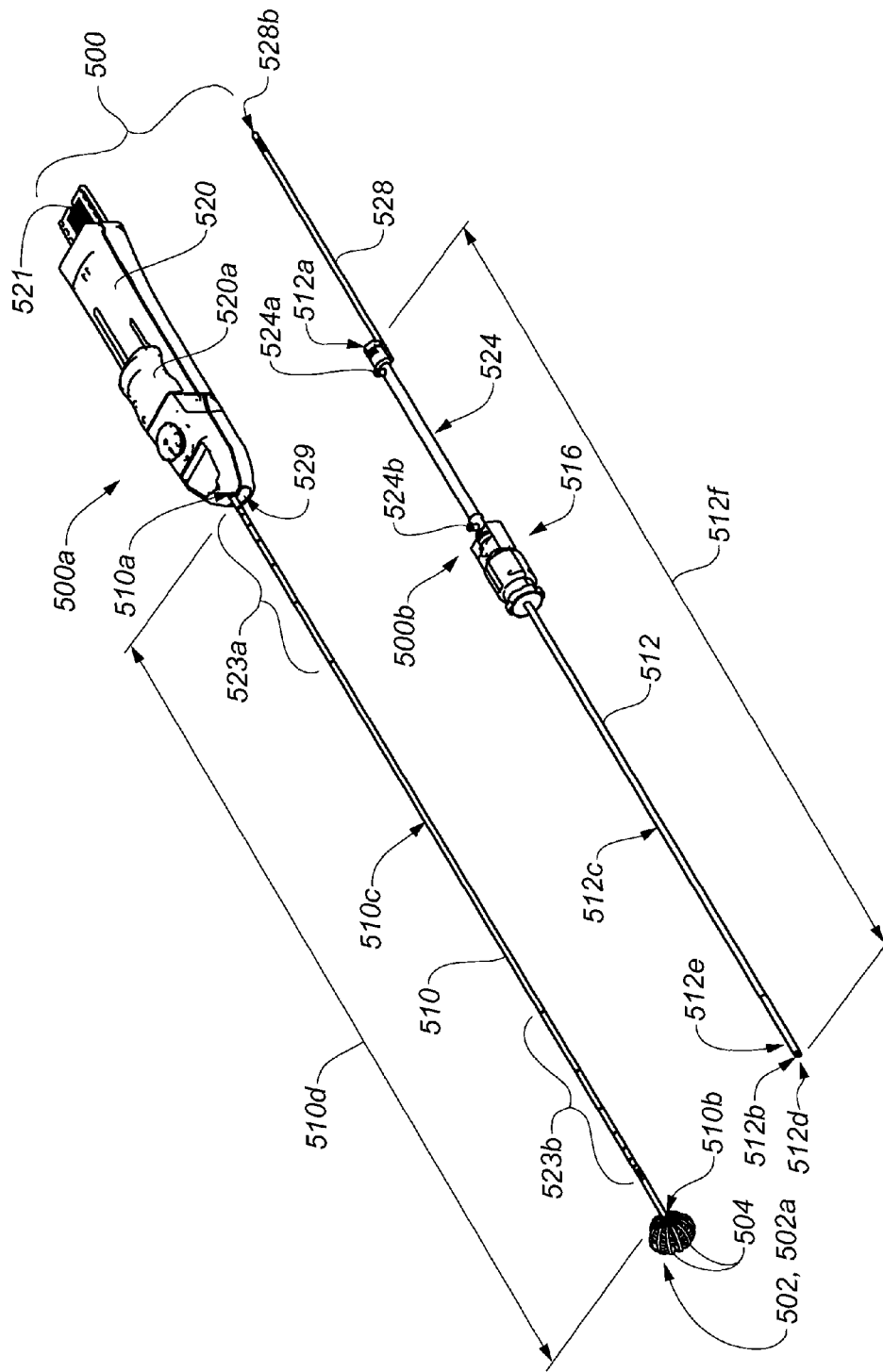


FIG. 5A

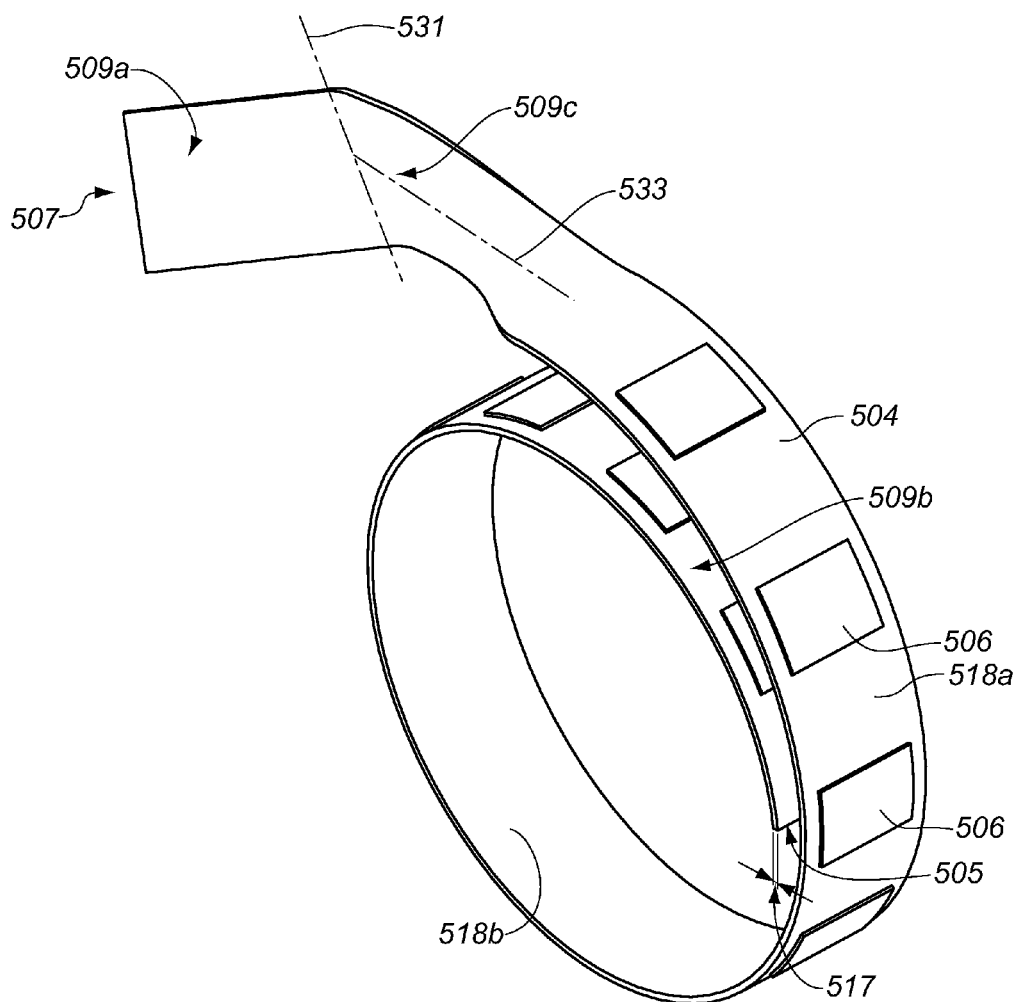


FIG. 5B

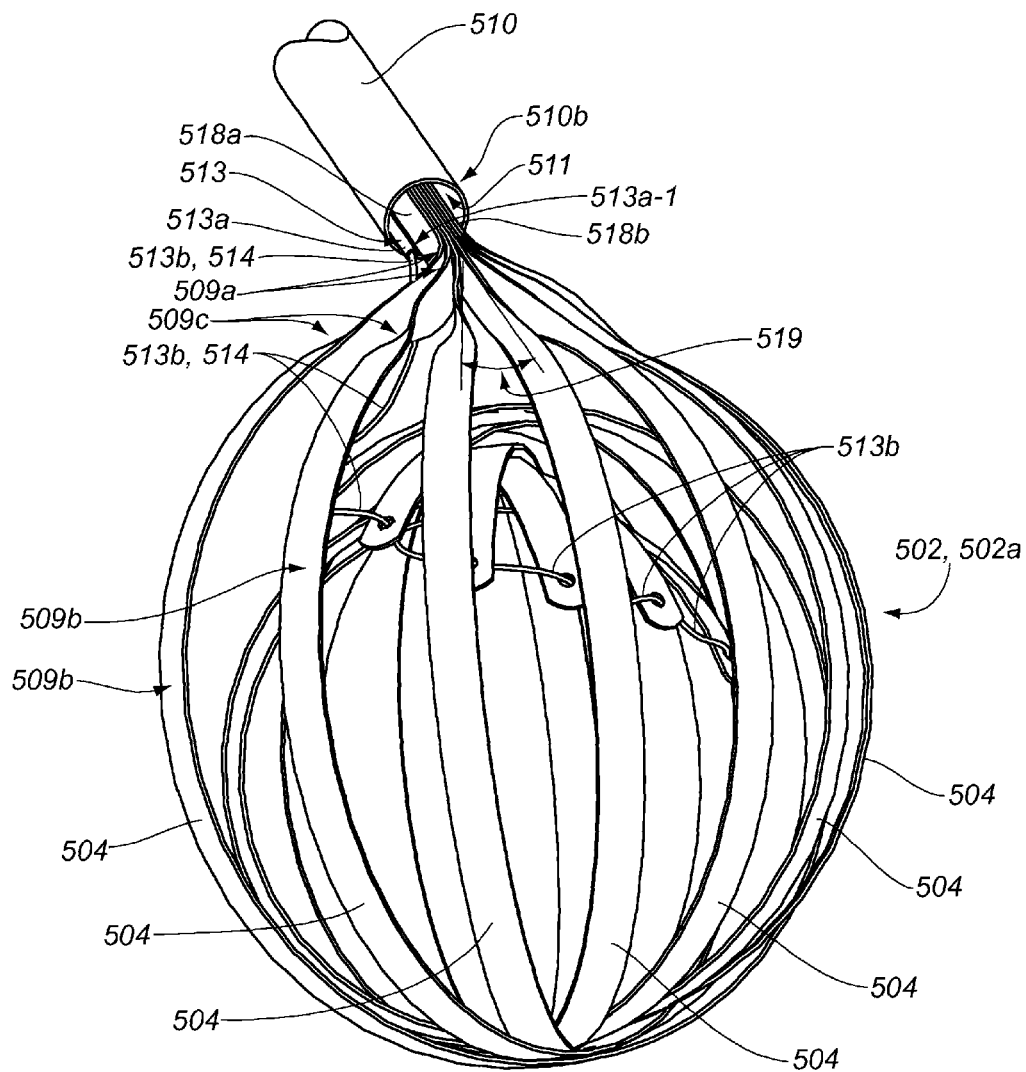


FIG. 5C

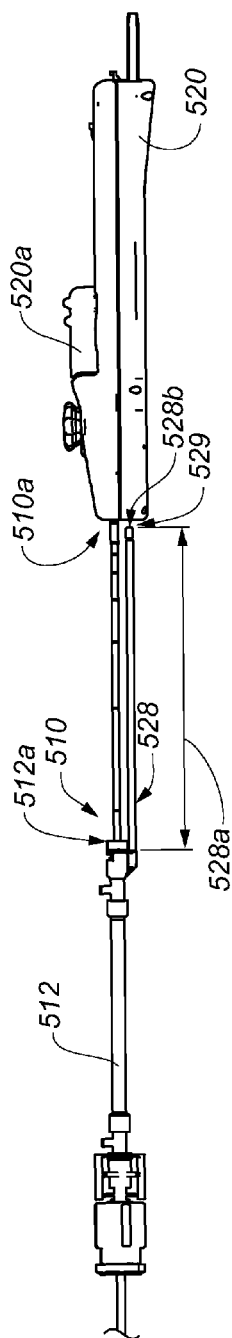


FIG. 5D

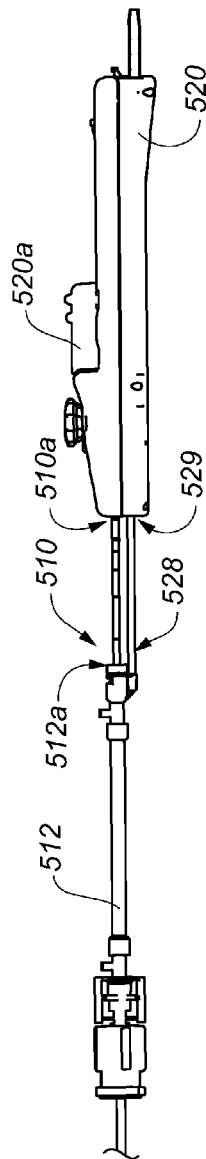


FIG. 5E

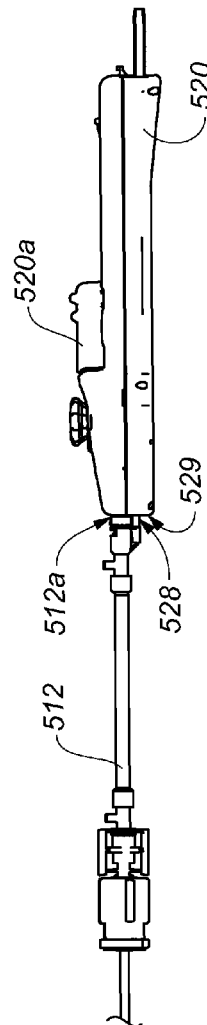


FIG. 5F

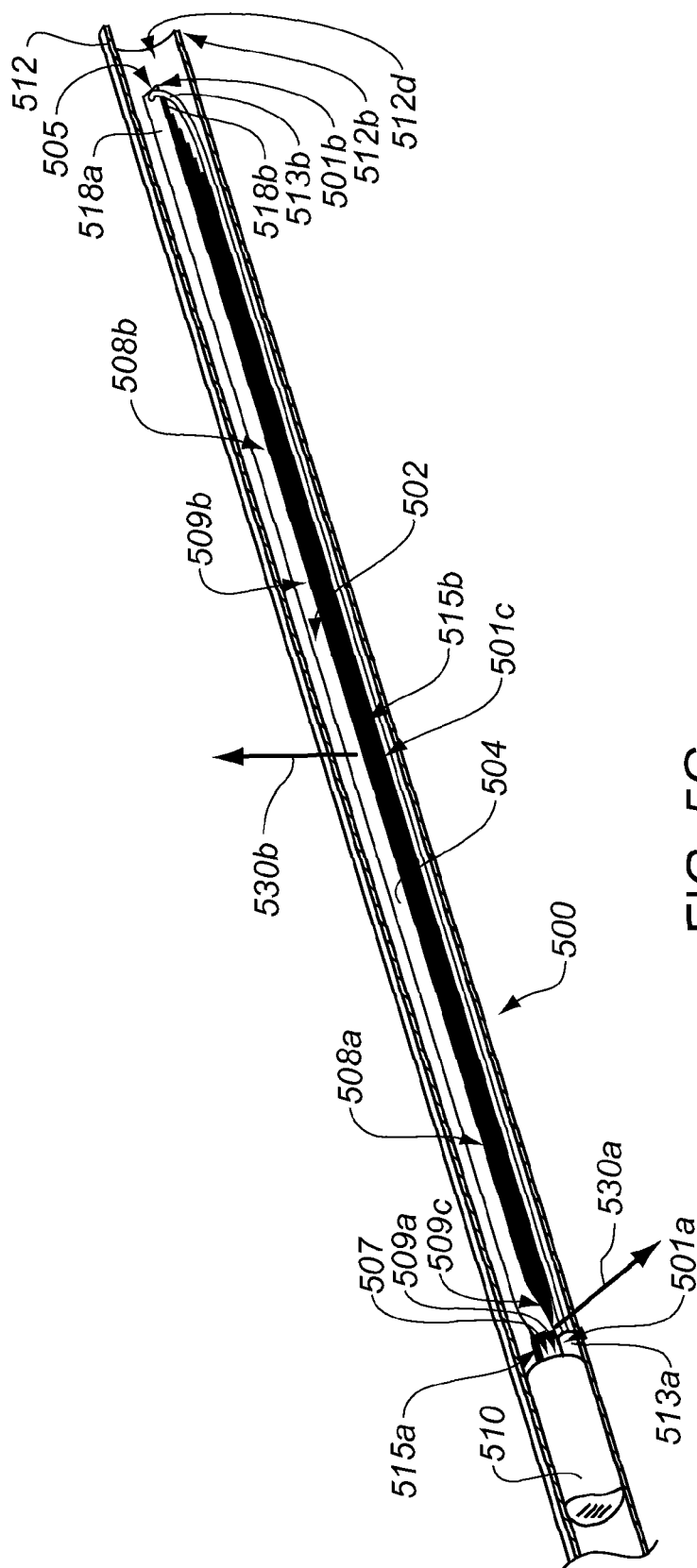
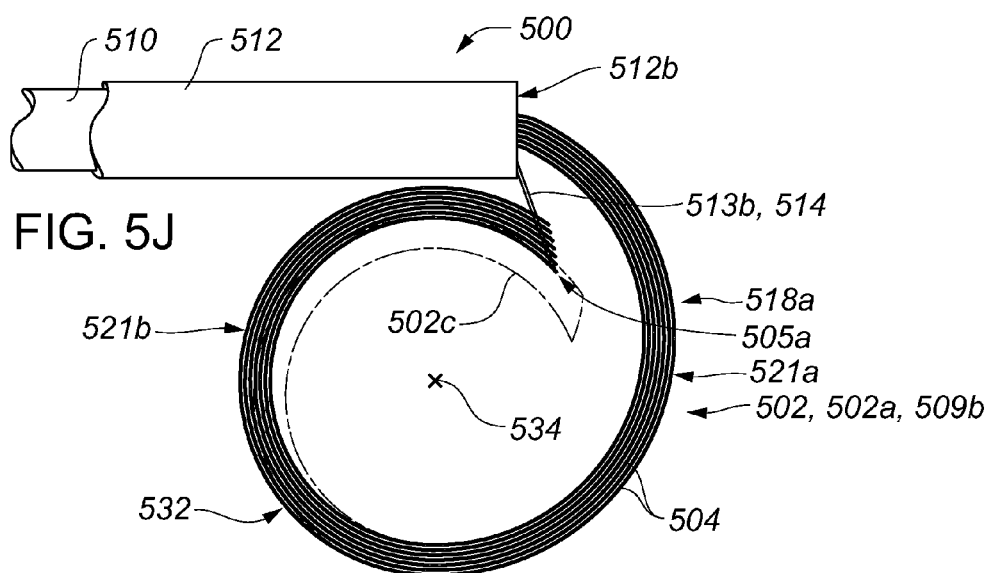
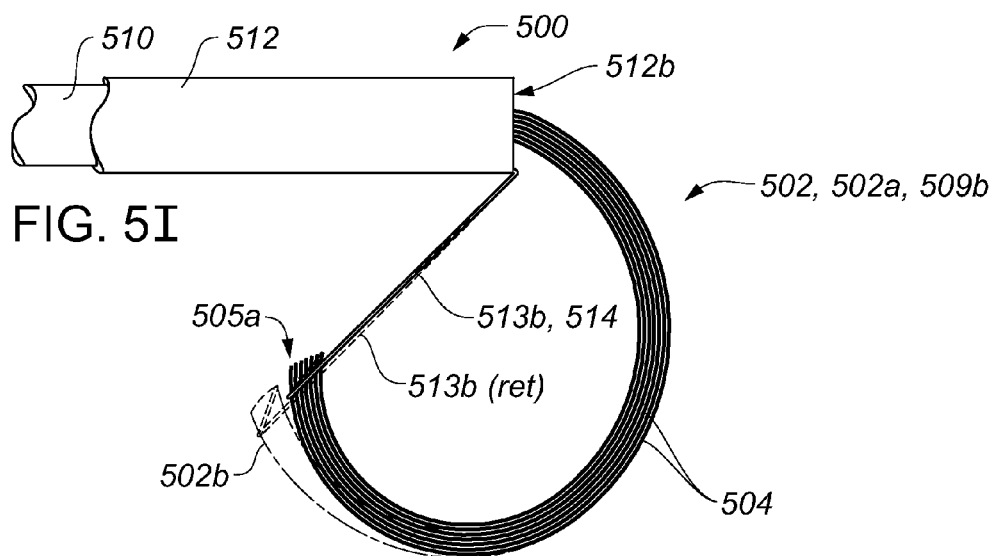
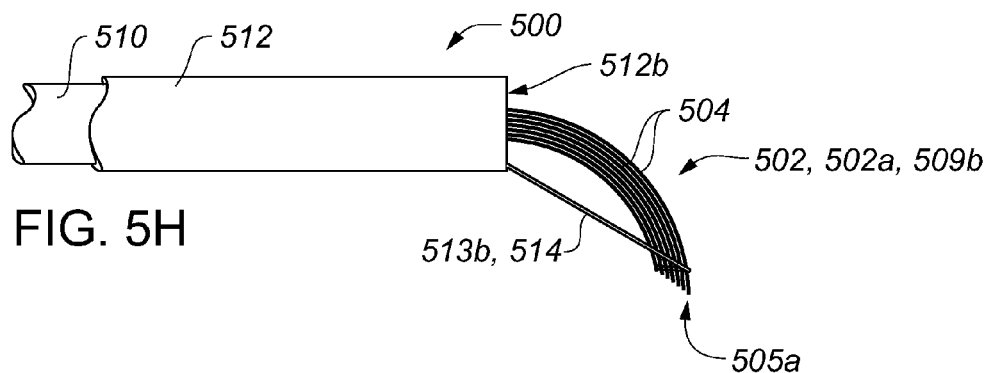


FIG. 5G



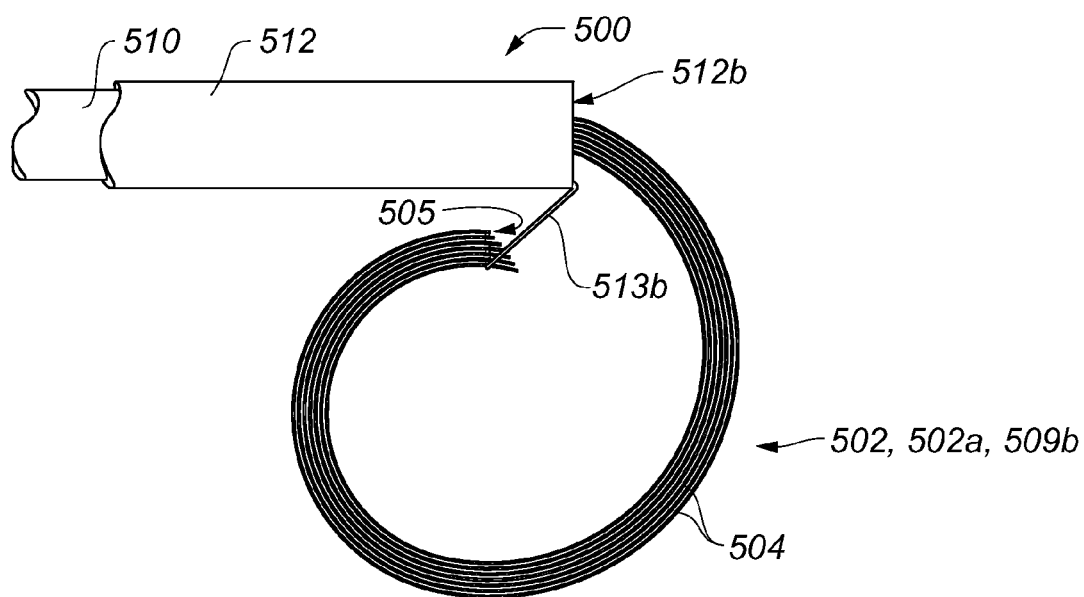


FIG. 5K

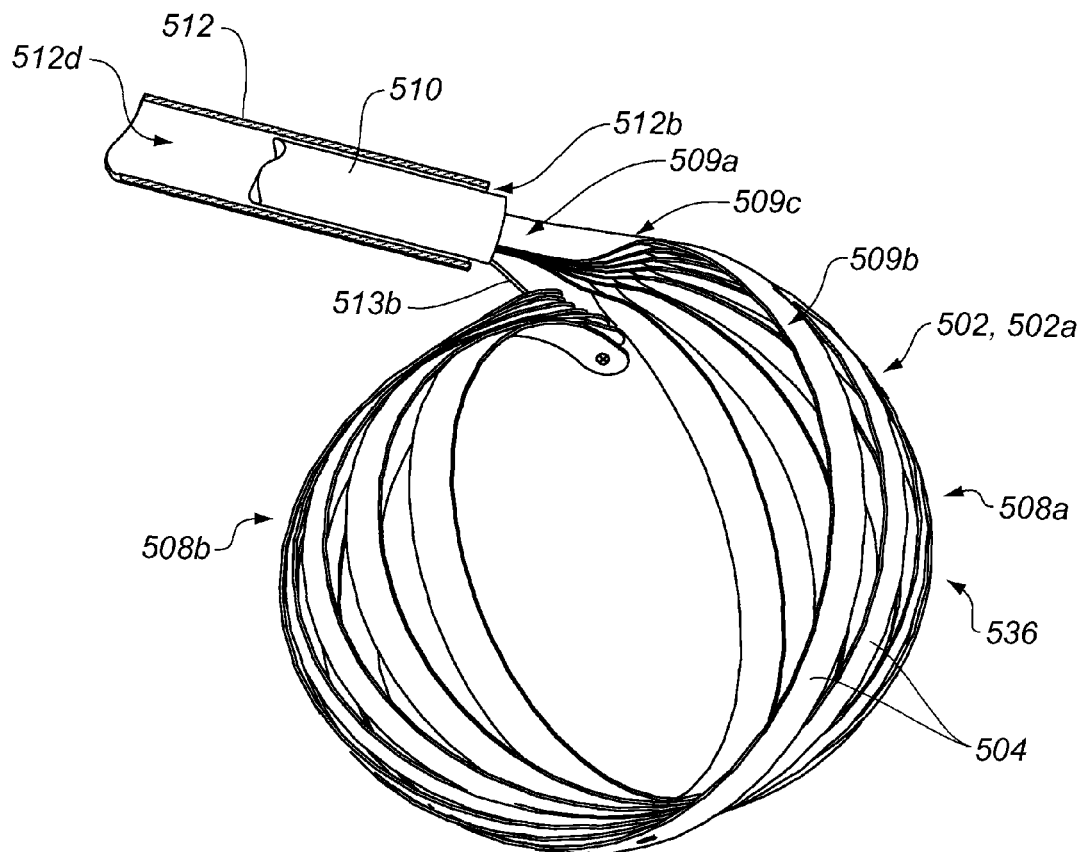


FIG. 5L-1

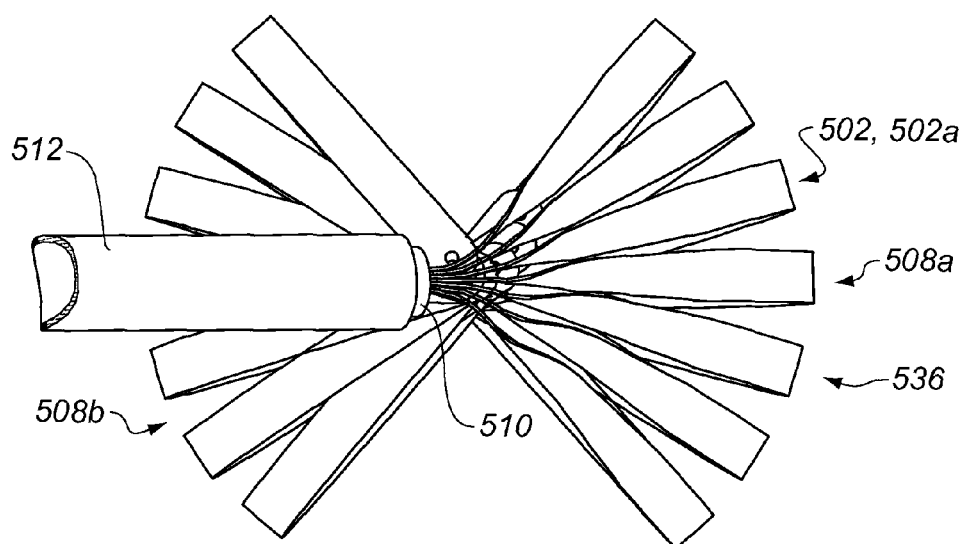


FIG. 5L-2

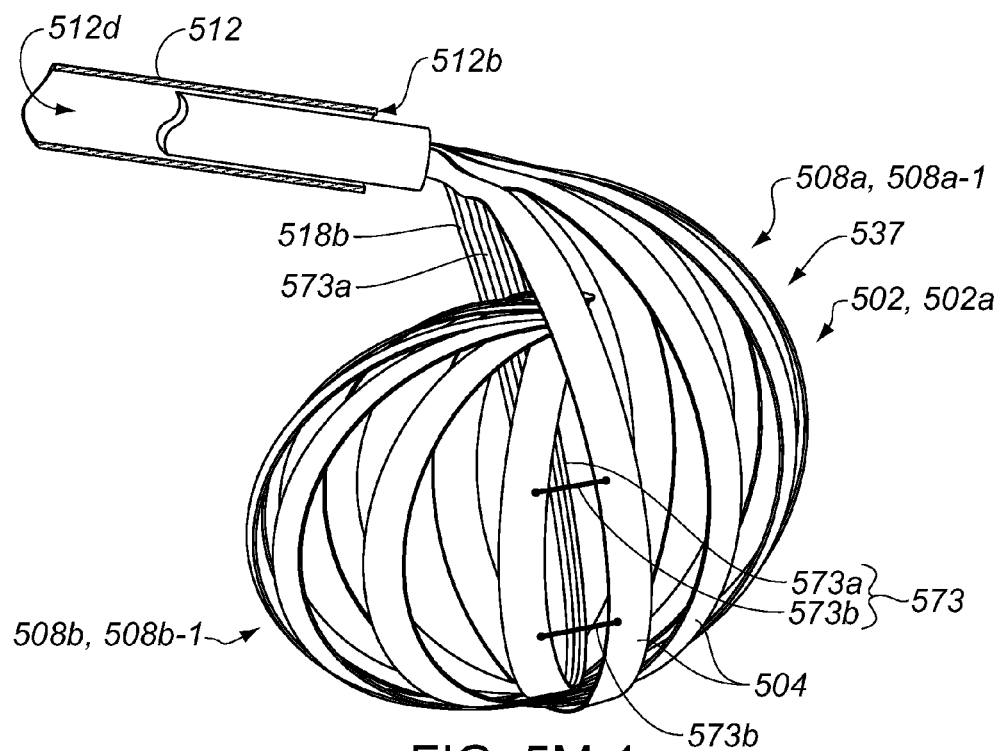


FIG. 5M-1

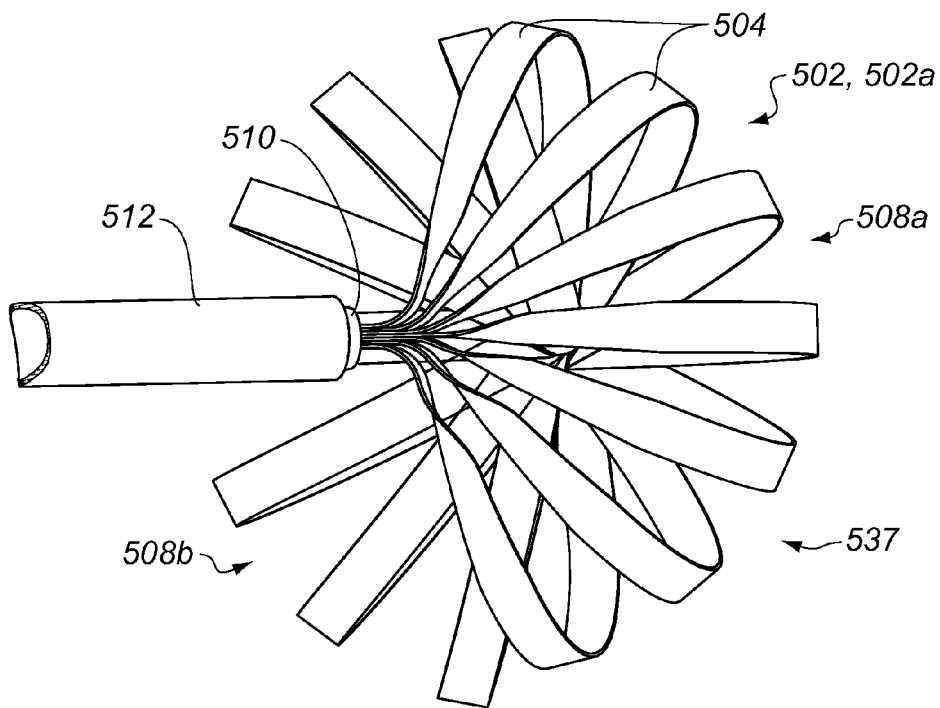


FIG. 5M-2

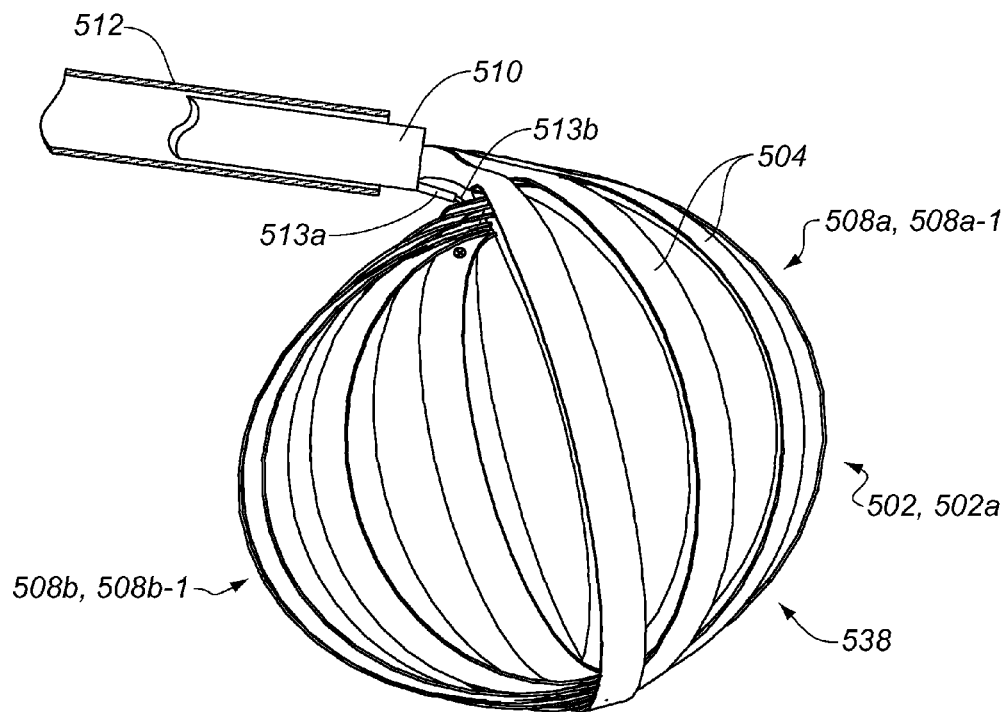


FIG. 5N

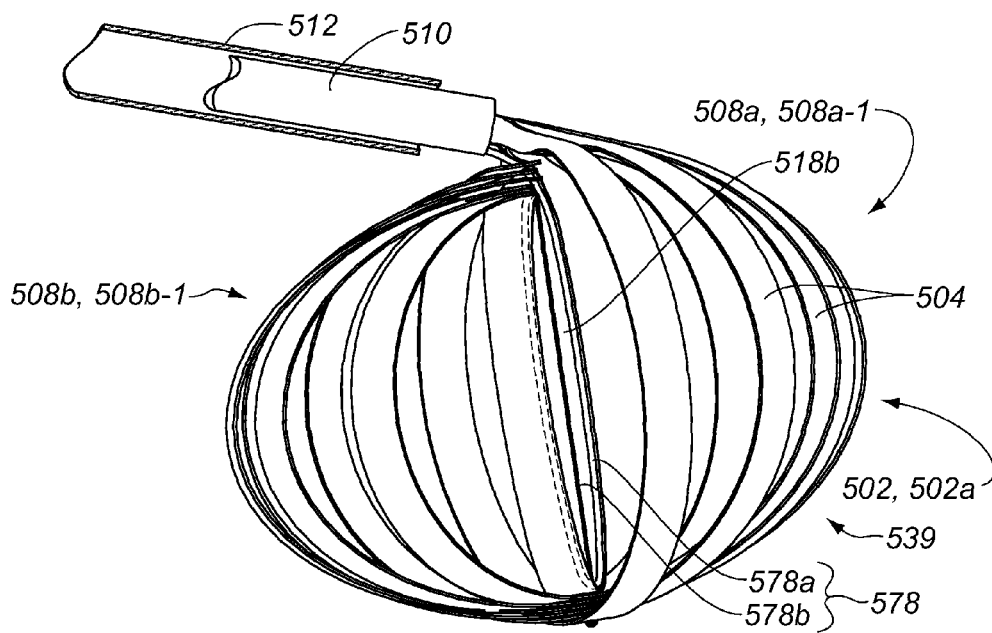


FIG. 5O

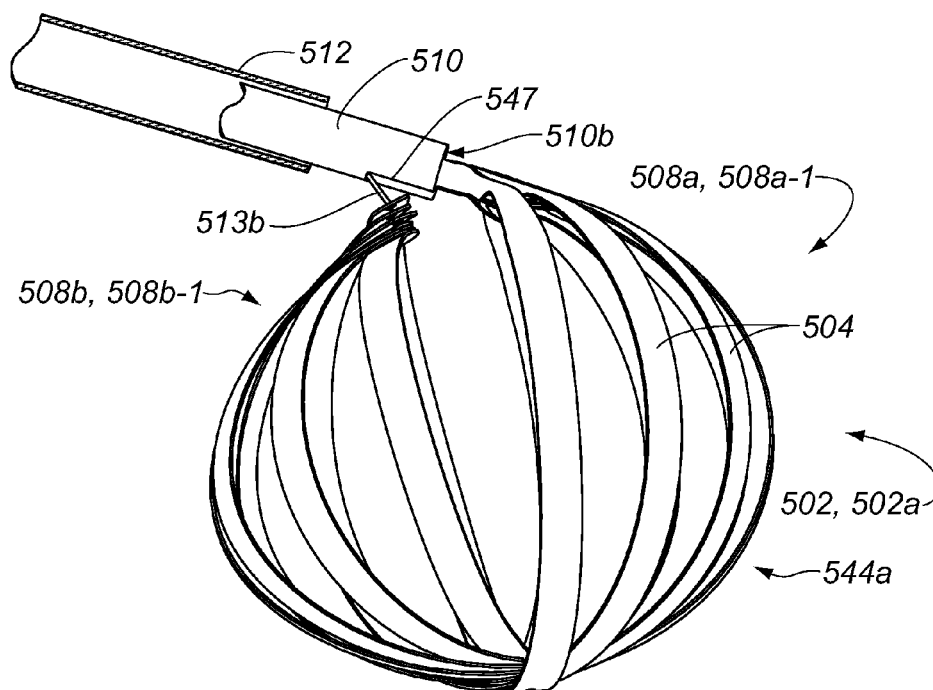


FIG. 5P

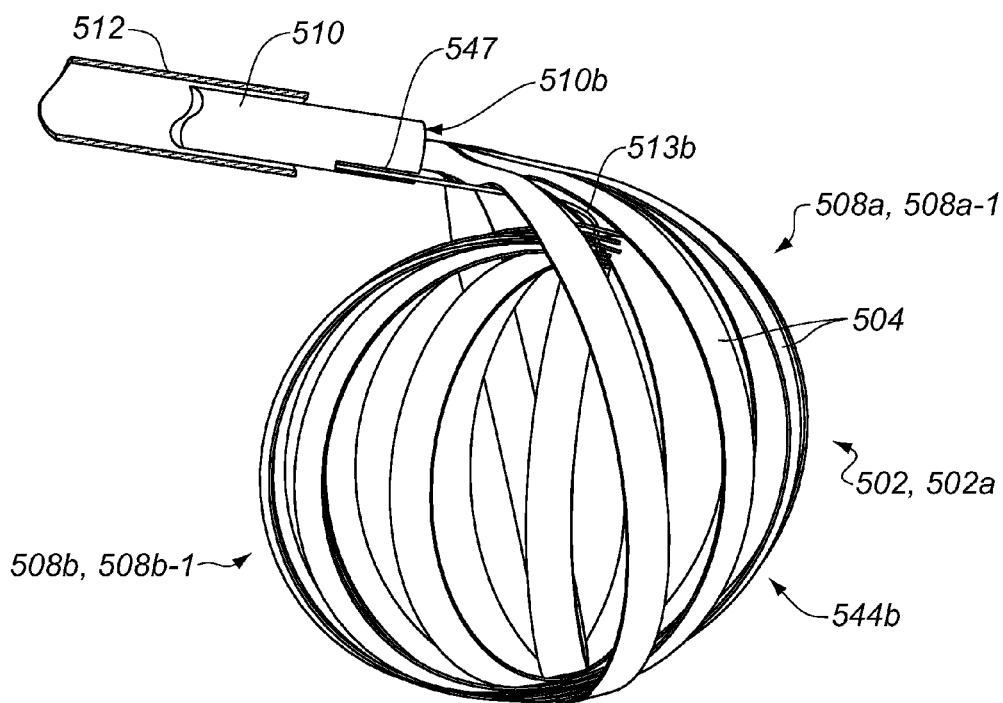
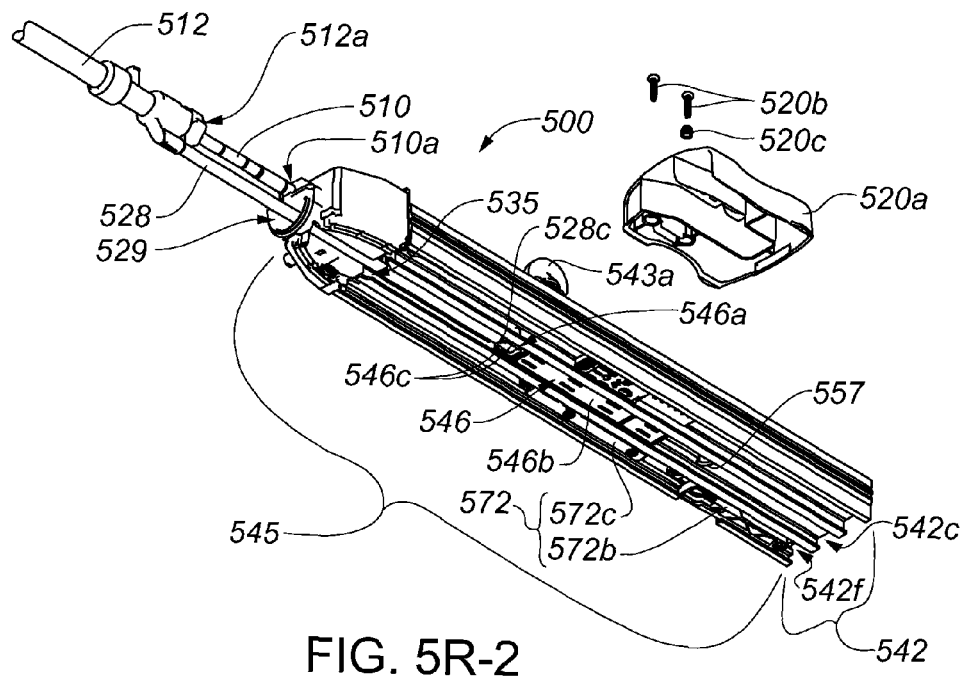
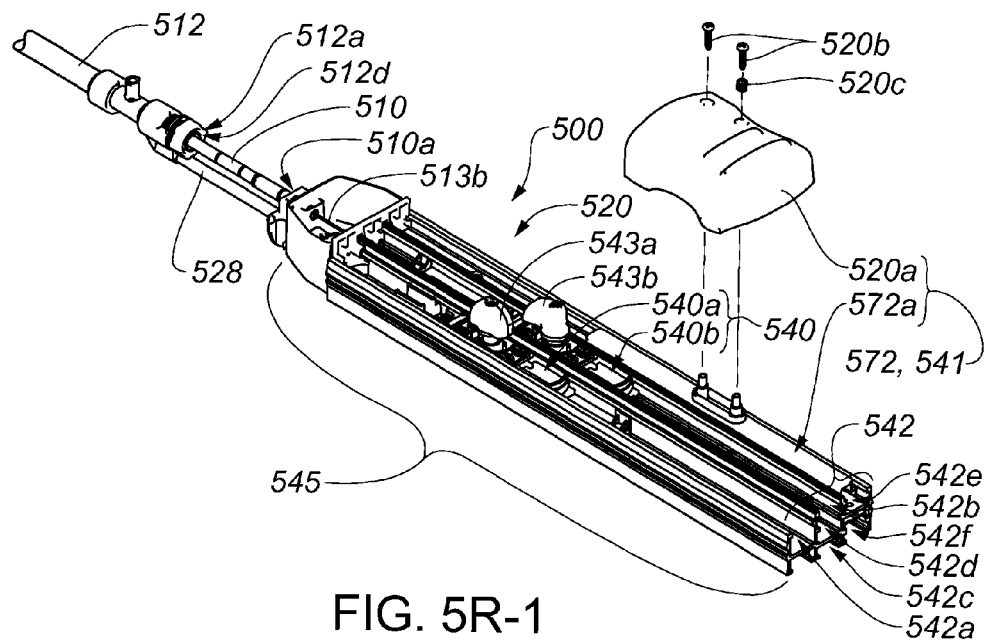


FIG. 5Q



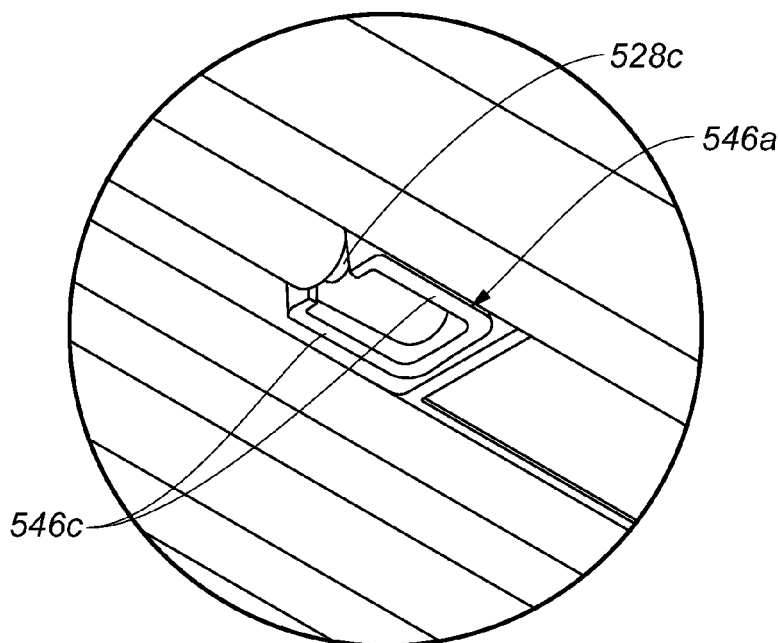


FIG. 5R-3

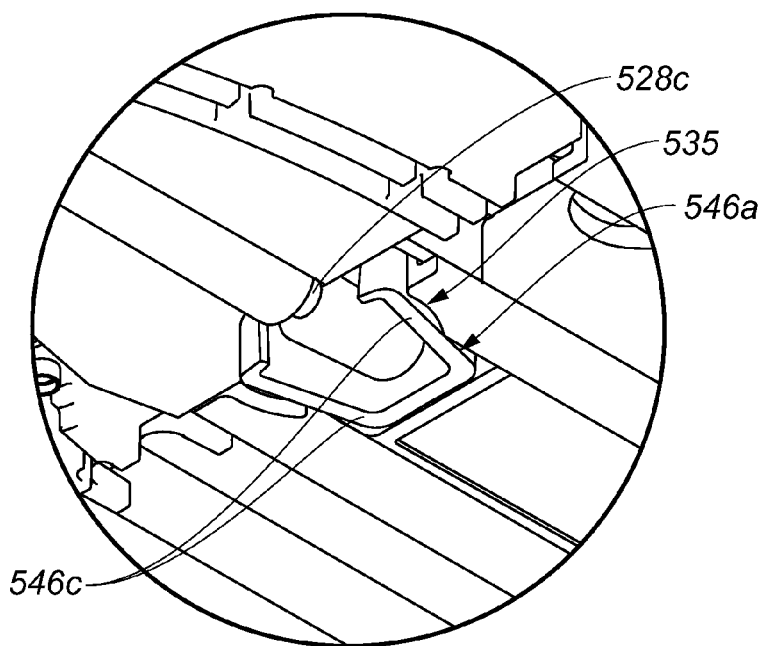


FIG. 5R-4

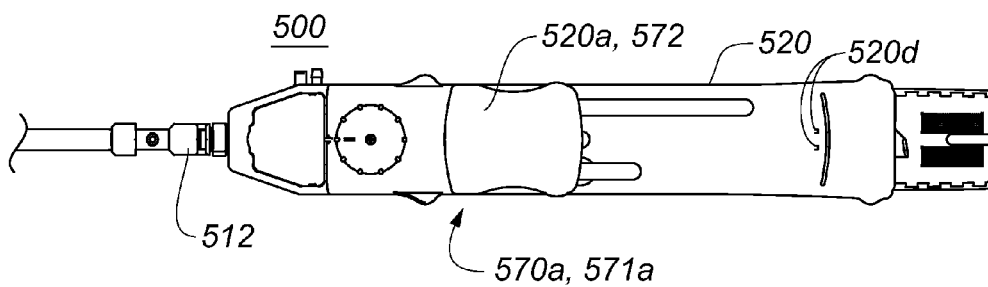


FIG. 5S-1

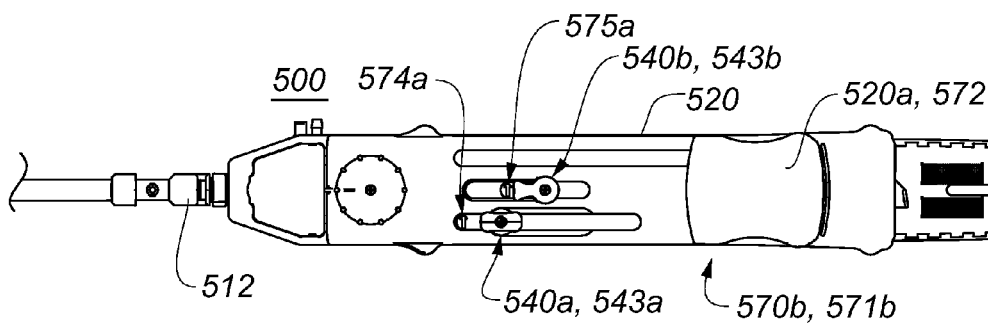


FIG. 5S-2

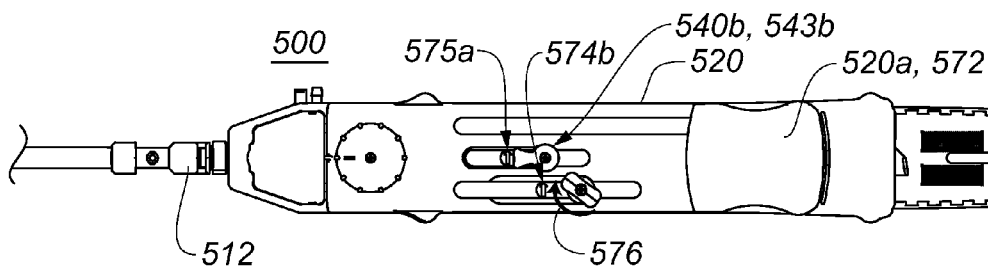


FIG. 5S-3

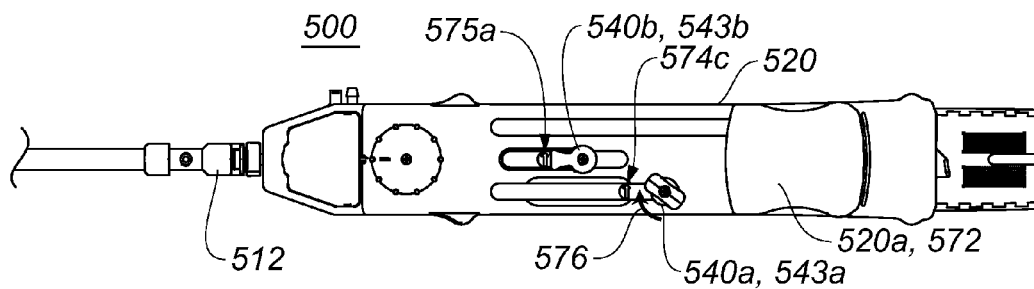


FIG. 5S-4

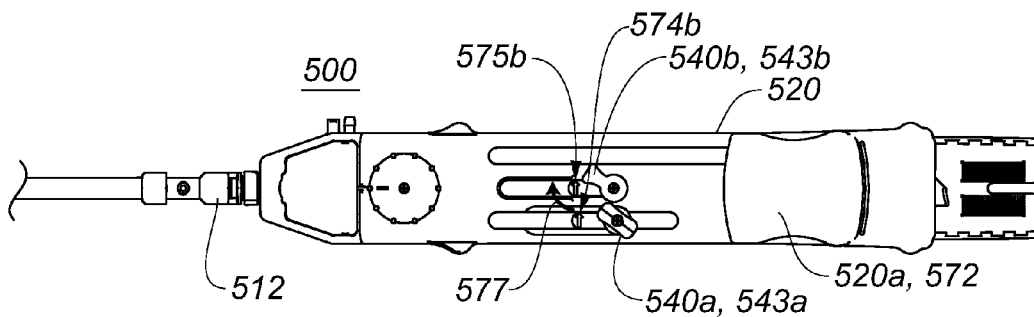


FIG. 5S-5

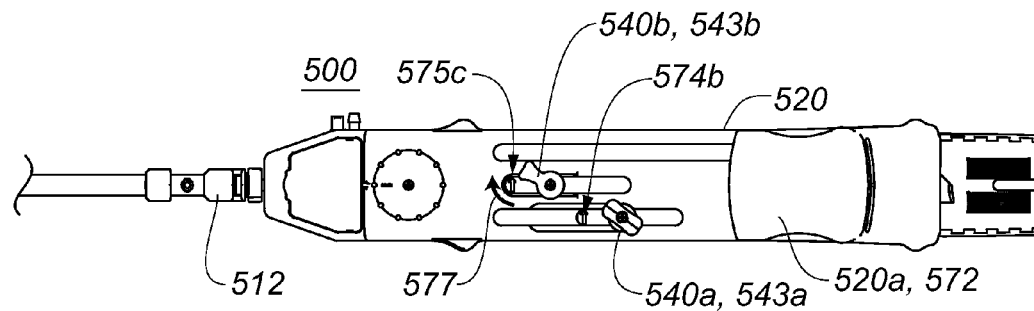


FIG. 5S-6

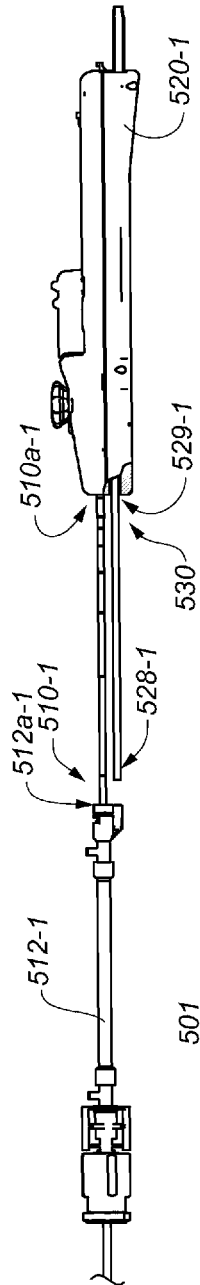


FIG. 5T

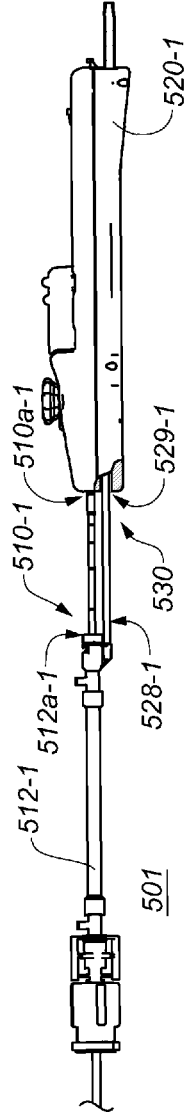


FIG. 5U

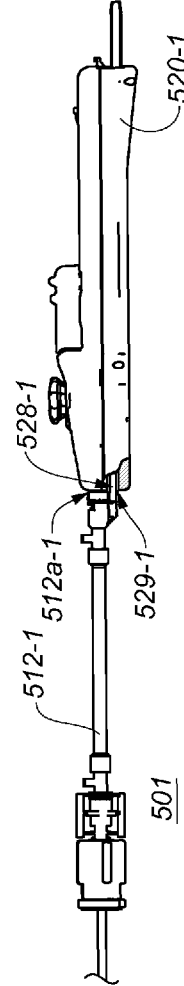
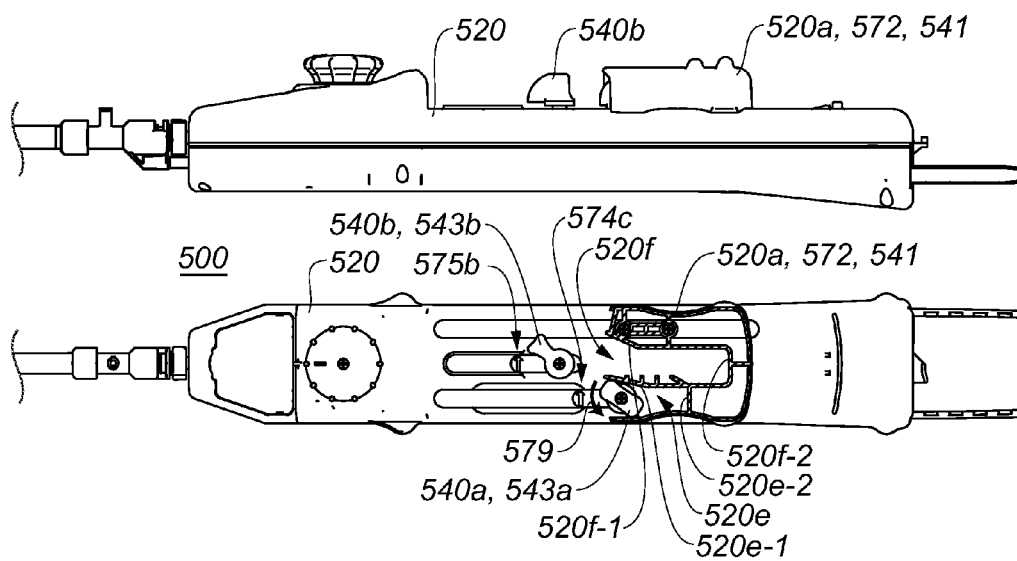
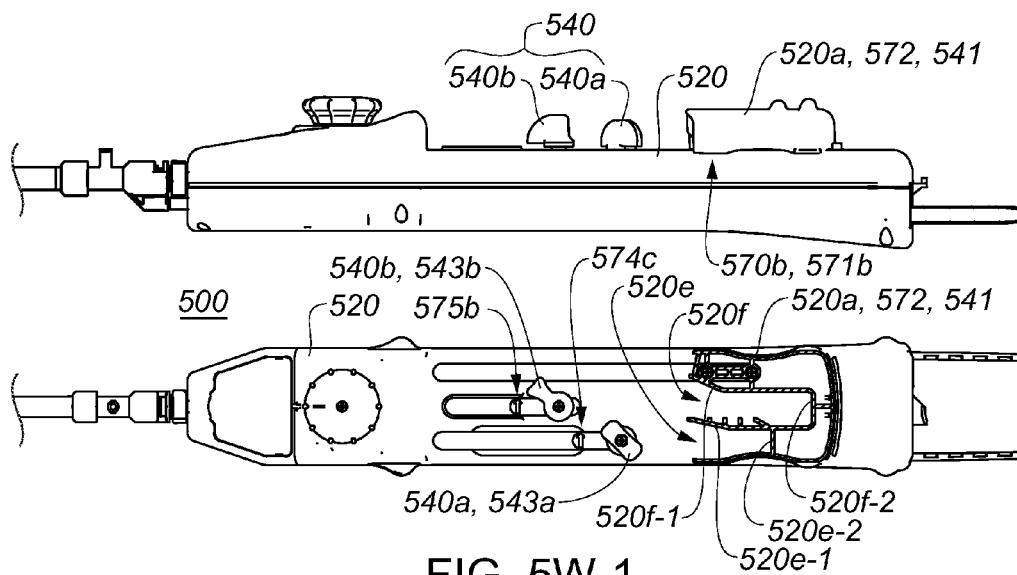


FIG. 5V



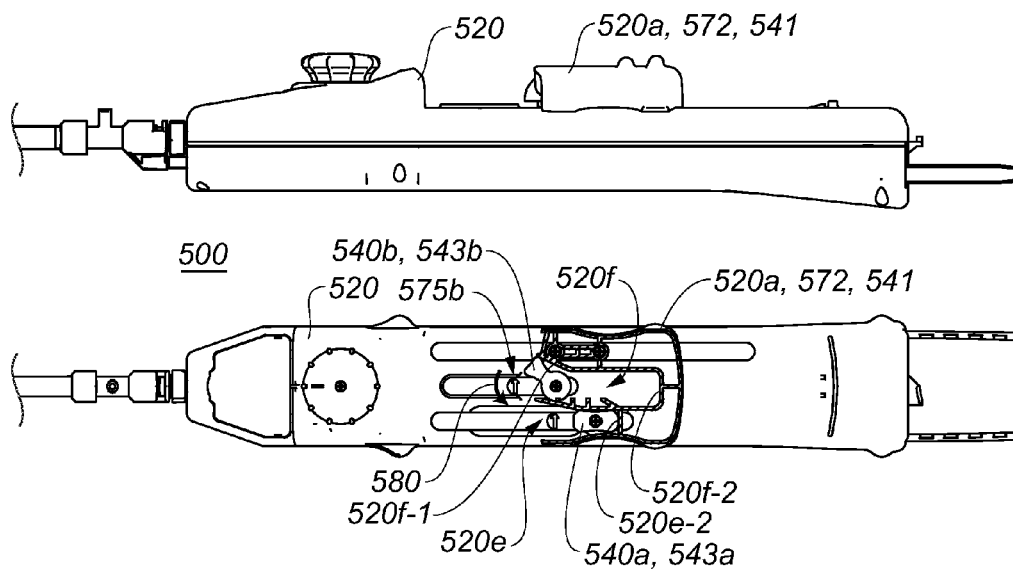


FIG. 5W-3

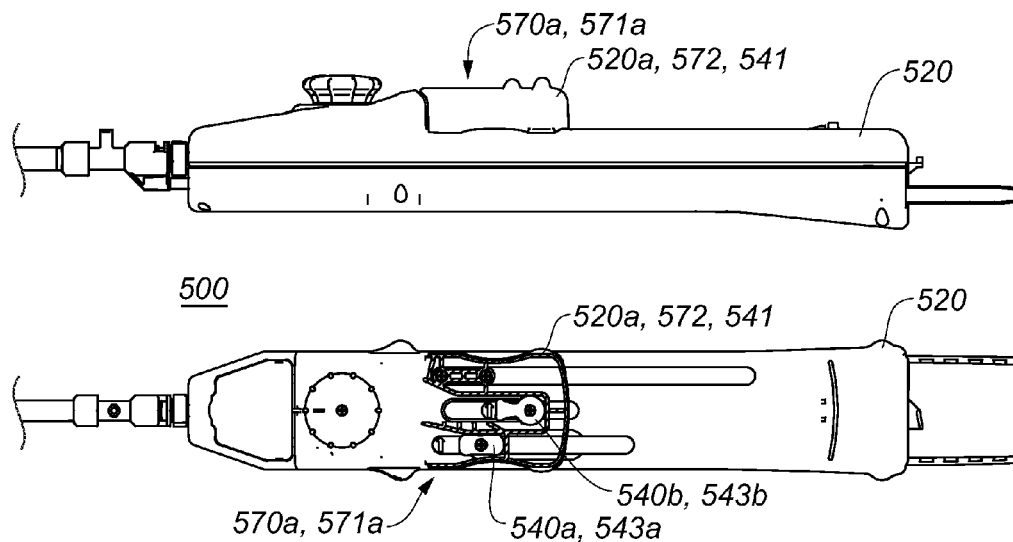


FIG. 5W-4

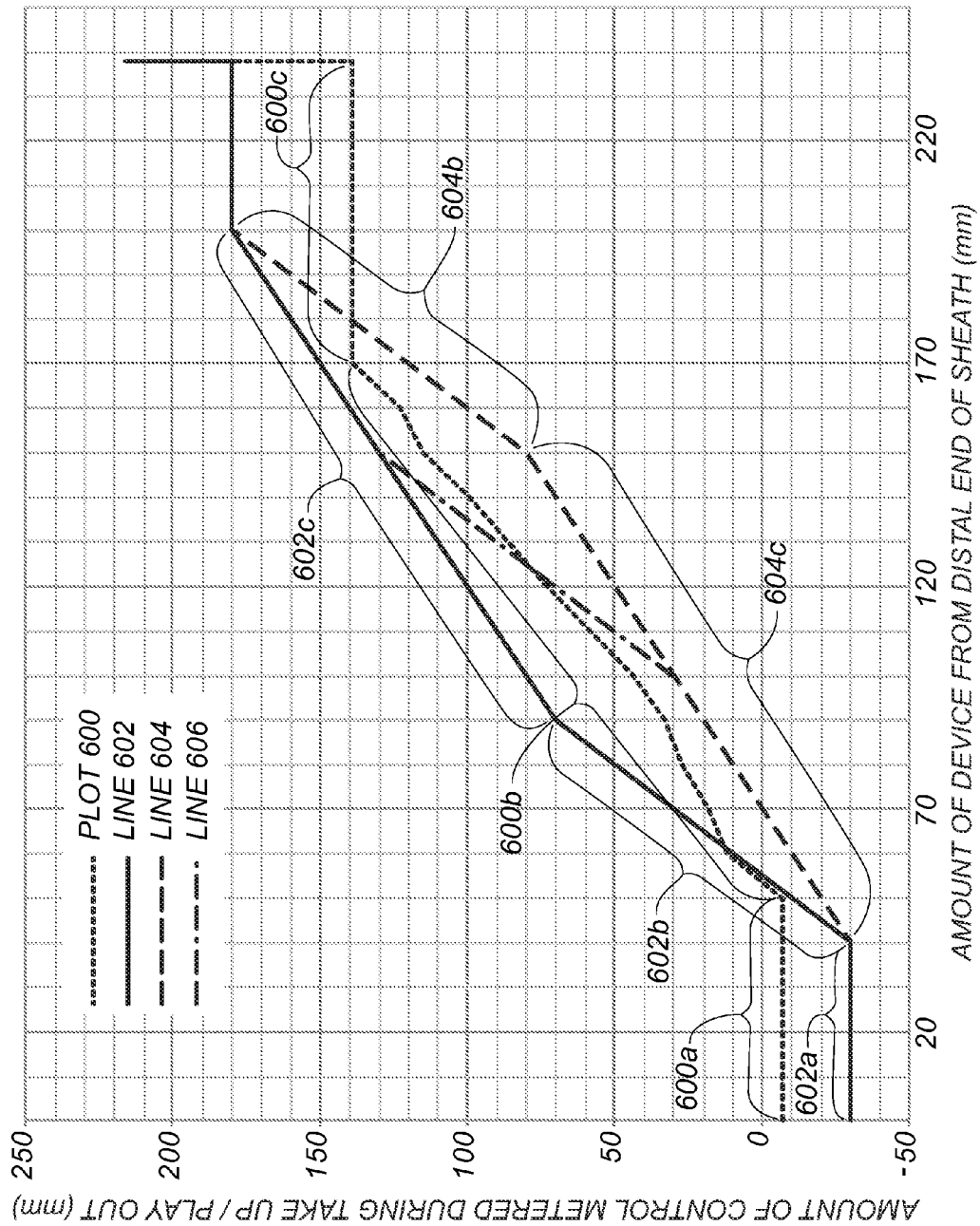
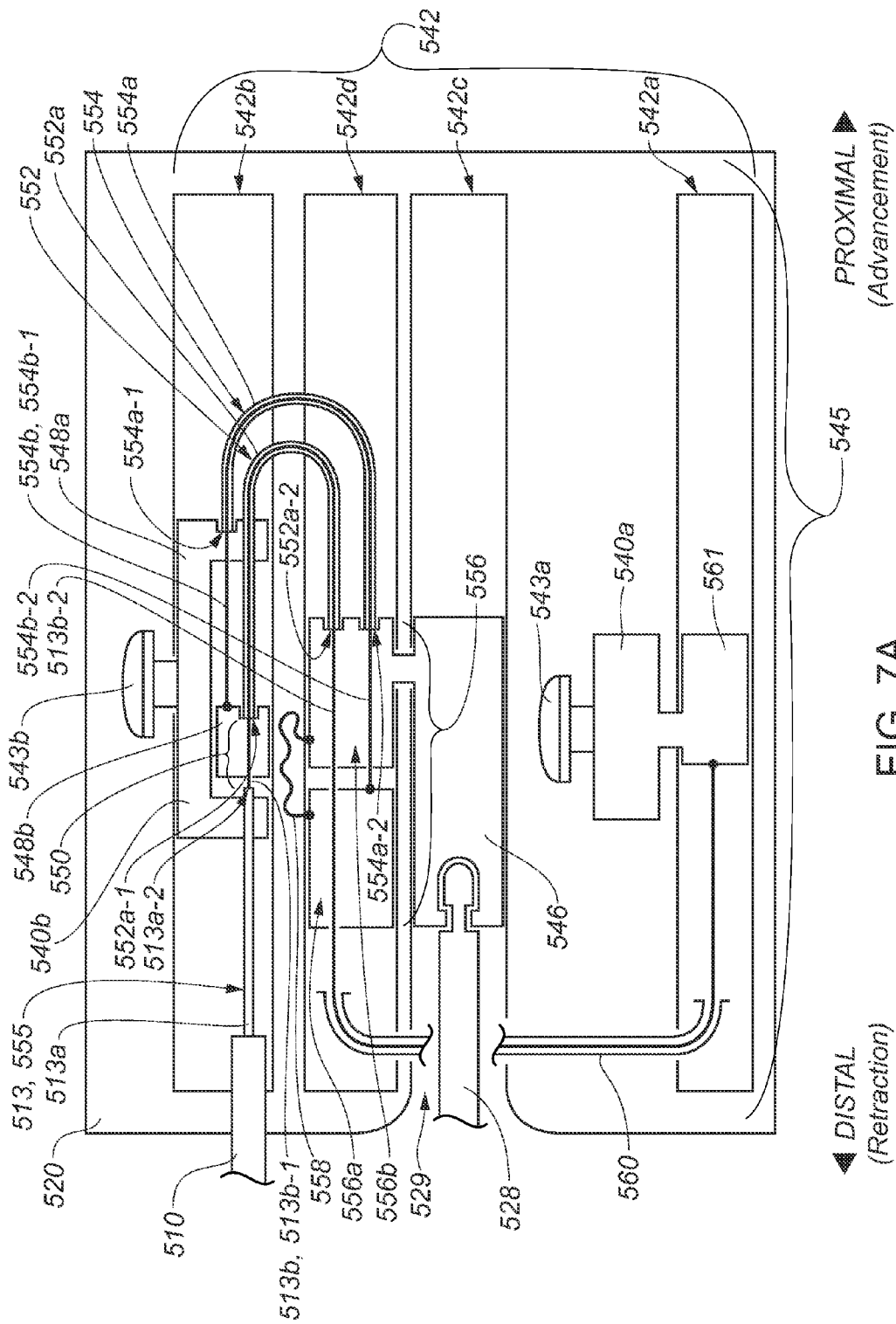
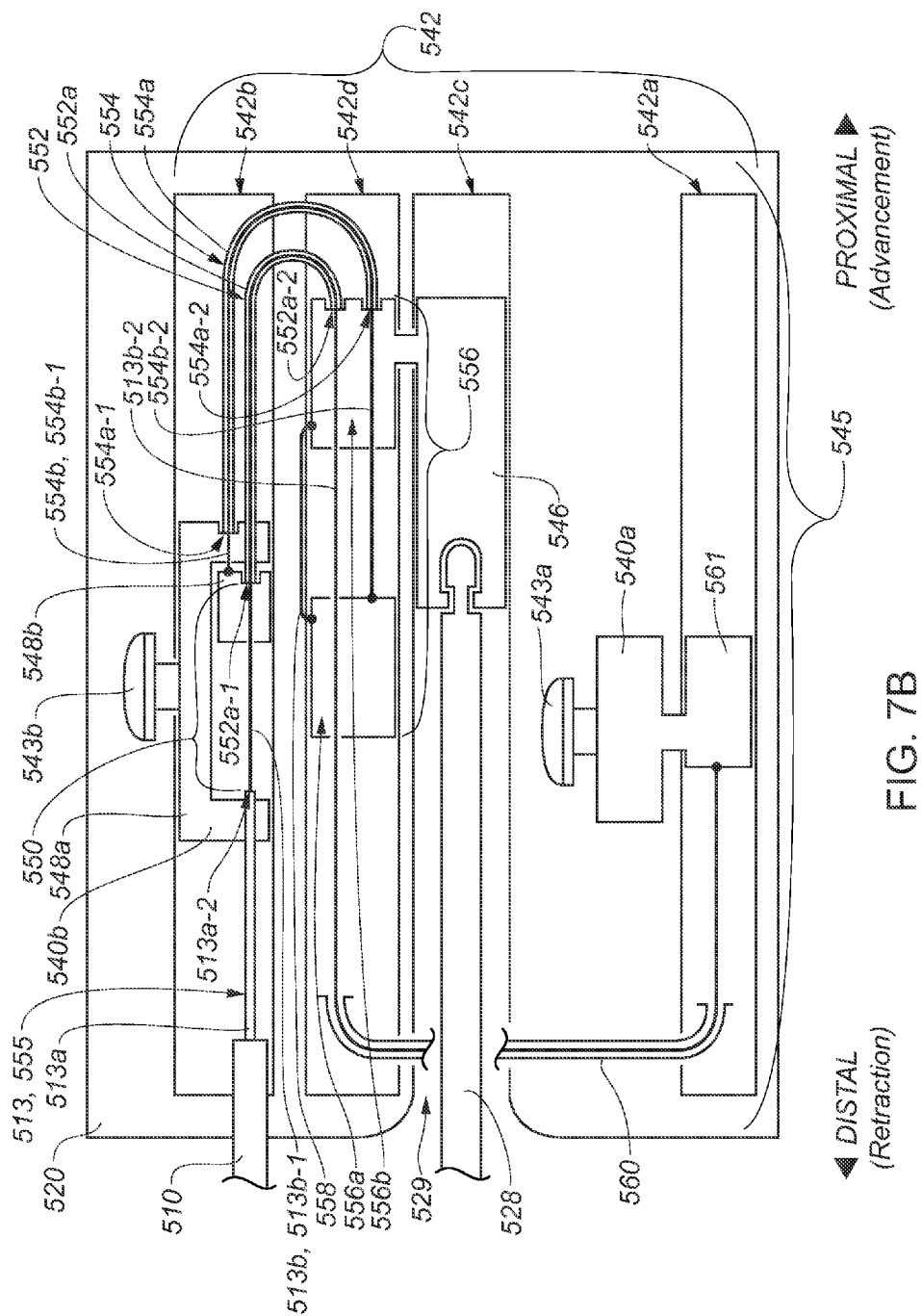
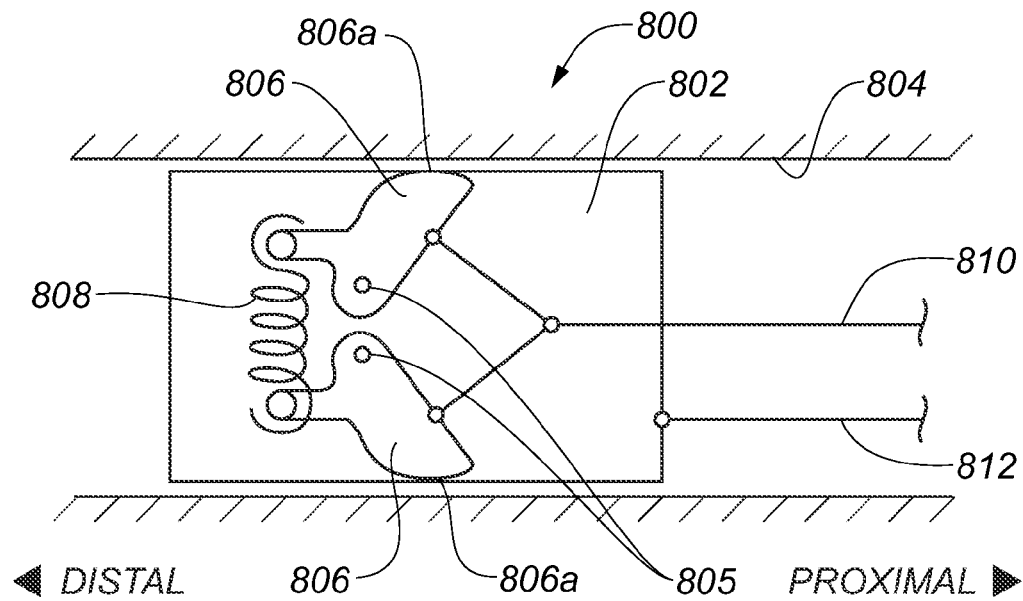
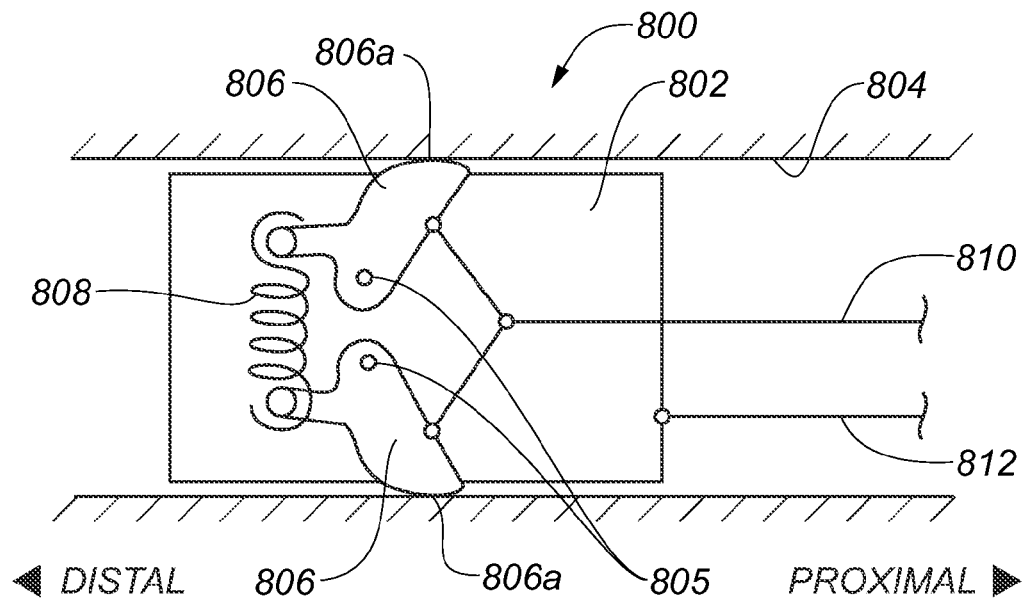


FIG. 6







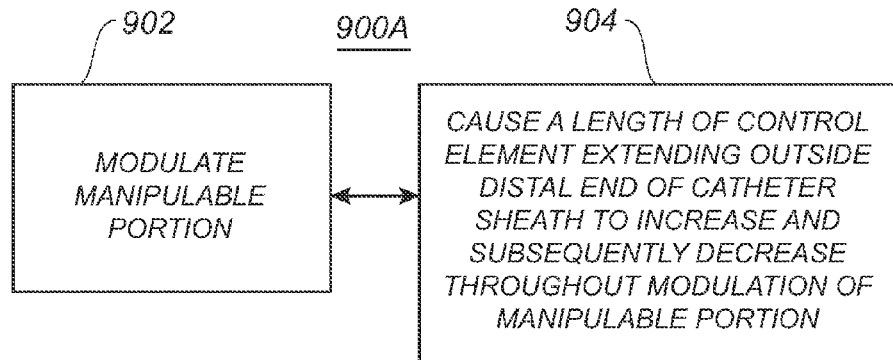


FIG. 9A

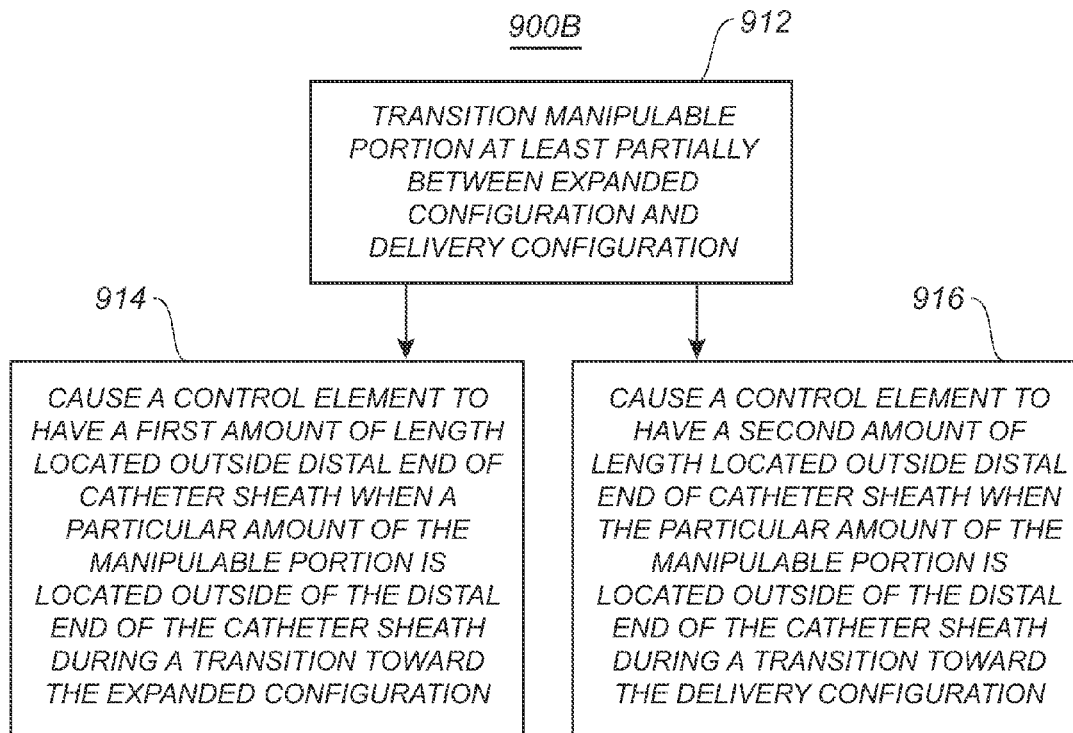


FIG. 9B

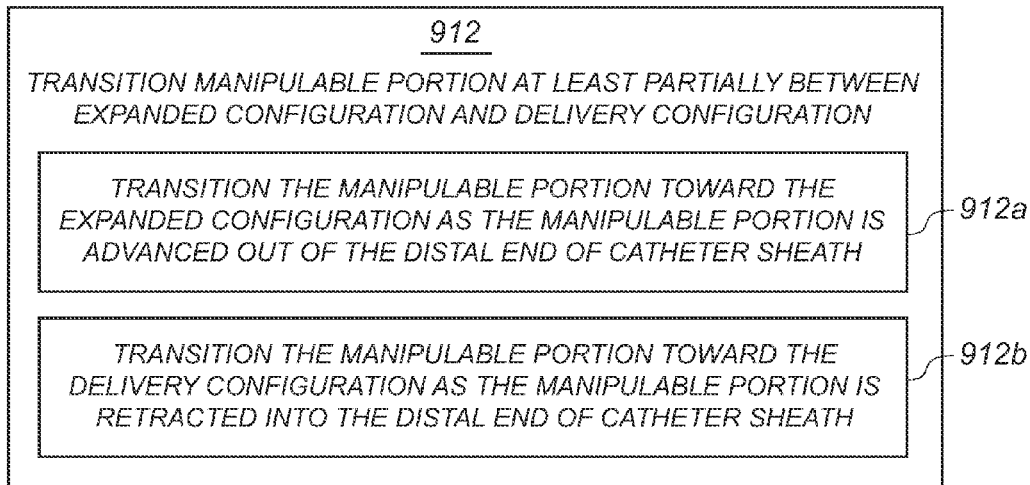


FIG. 9C

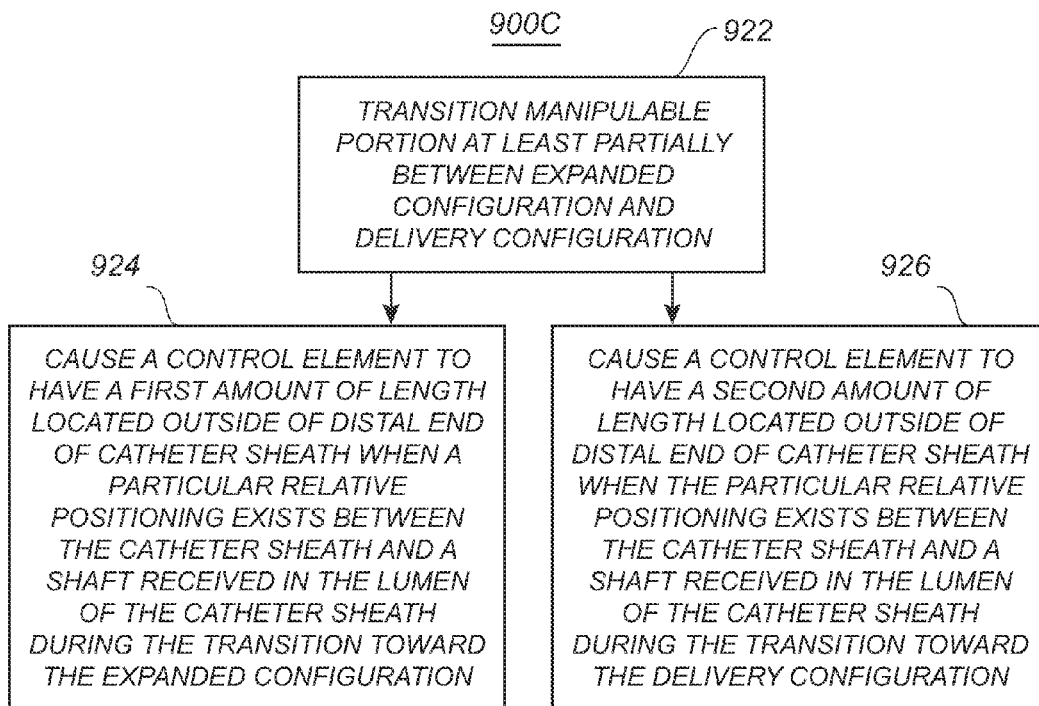


FIG. 9D

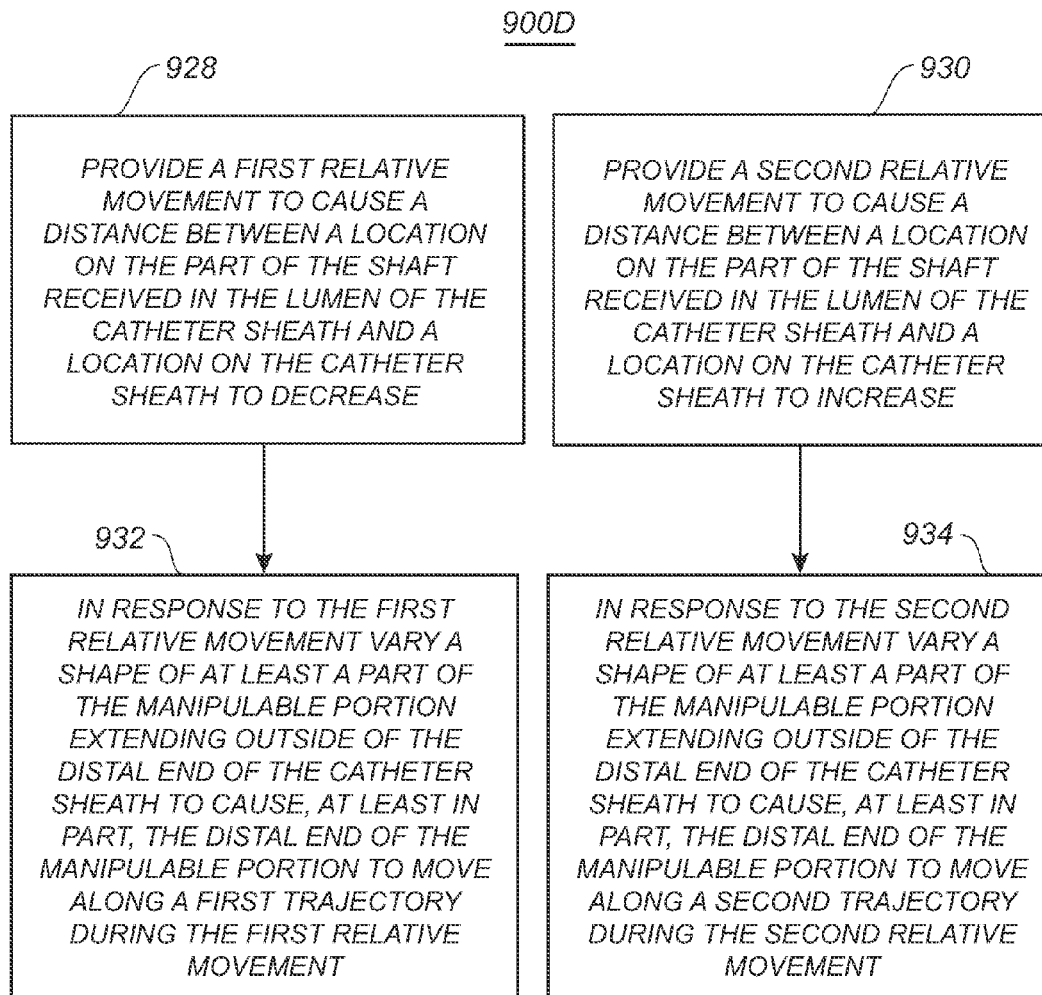


FIG. 9E

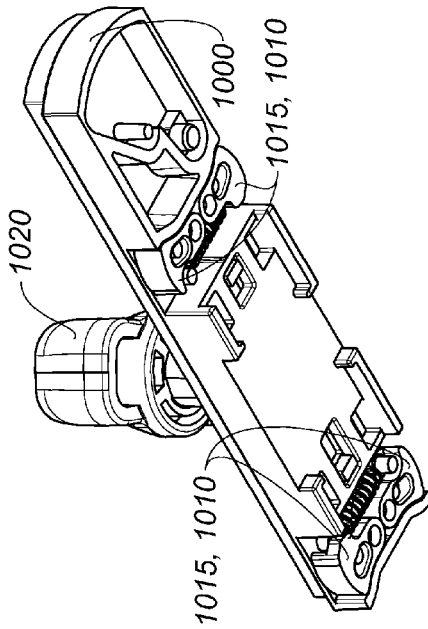


FIG. 10A

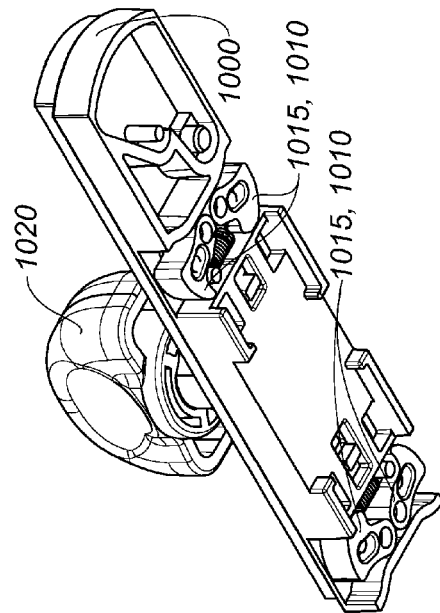


FIG. 10B

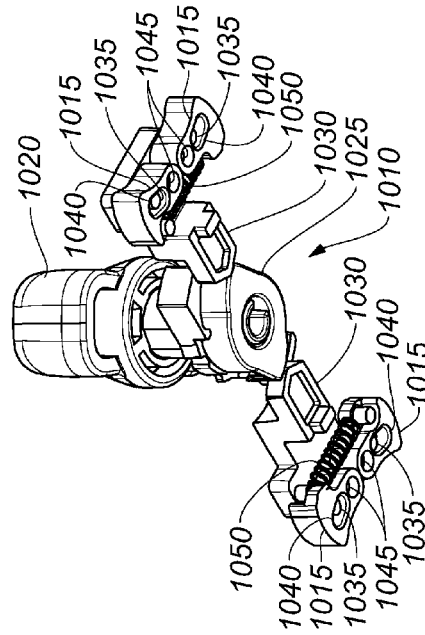


FIG. 10C

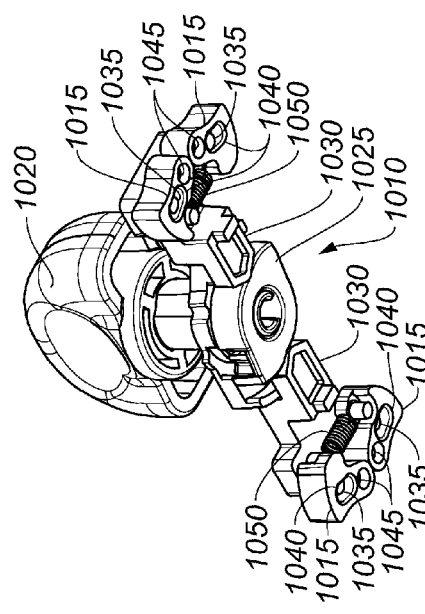


FIG. 10D

1

CATHETER SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 13/942,354, filed Jul. 15, 2013, which is a continuation of International Patent Application PCT/US2012/022061, filed Jan. 20, 2012, which claims the benefit of U.S. Provisional Application No. 61/435,213, filed Jan. 21, 2011; U.S. Provisional Application No. 61/485,987, filed May 13, 2011; U.S. Provisional Application No. 61/488,639, filed May 20, 2011; and U.S. Provisional Application No. 61/515,141, filed Aug. 4, 2011. This application also is related to a U.S. provisional application Ser. No. 61/919,388 filed on even date herewith with the title, "MEDICAL SYSTEM", with the same inventors as the present application, and bearing an attorney docket number of "KARD-0004US1B-PRO". The entire disclosure of each of the applications cited in this Cross-Reference to Related Applications Section is hereby incorporated herein by reference.

TECHNICAL FIELD

Aspects of this disclosure generally are related to a medical system, such as a catheter system including a catheter sheath and an elongated catheter sized for delivery through a lumen of the catheter sheath. In some embodiments, the catheter system includes a controllable manipulable portion.

BACKGROUND

Cardiac surgery was initially undertaken using highly invasive open procedures. A sternotomy, which is a type of incision in the center of the chest that separates the sternum, was typically employed to allow access to the heart. In the past several decades, more and more cardiac operations are performed using intravascular or percutaneous techniques, where access to inner organs or other tissue is gained via a catheter.

Intravascular or percutaneous surgeries benefit patients by reducing surgery risk, complications and recovery time. However, the use of intravascular or percutaneous technologies also raises some particular challenges. Medical devices used in intravascular or percutaneous surgery need to be deployed via catheter systems which significantly increase the complexity of the device structure. As well, doctors do not have direct visual contact with the medical devices once the devices are positioned within the body.

One example of where intravascular or percutaneous medical techniques have been employed is in the treatment of a heart disorder called atrial fibrillation. Atrial fibrillation is a disorder in which spurious electrical signals cause an irregular heartbeat. Atrial fibrillation has been treated with open heart methods using a technique known as the "Cox-Maze procedure". During various procedures, health care providers create specific patterns of lesions in the left or right atria to block various paths taken by the spurious electrical signals. Such lesions were originally created using incisions, but are now typically created by ablating the tissue with various techniques including radio-frequency (RF) energy, microwave energy, laser energy and cryogenic techniques. The procedure is performed with a high success rate under the direct vision that is provided in open procedures, but is relatively complex to perform intravascularly or

2

percutaneously because of the difficulty in creating the lesions in the correct locations. Various problems, potentially leading to severe adverse results, may occur if the lesions are placed incorrectly. It is particularly important to know the position of the various transducers which will be creating the lesions relative to cardiac features such as the pulmonary veins and mitral valve. The continuity, transmural, and placement of the lesion patterns that are formed can impact the ability to block paths taken within the heart by spurious electrical signals. Other requirements for various ones of the transducers to perform additional functions such as, but not limited to, mapping various anatomical features, mapping electrophysiological activity, sensing tissue characteristics such as impedance and temperature, and tissue stimulation can also complicate the operation of the employed medical device.

Conventional catheter systems have technological limitations that limit effective manipulation of a portion thereof in intra-bodily cavities and, consequently, have difficulty ensuring proper deployment, properly gathering adequate information, or performing proper lesion formation. Accordingly, a need in the art exists for catheter systems having improved manipulation capabilities.

SUMMARY

At least the above-discussed need is addressed and technical solutions are achieved by various embodiments of the present invention. In some embodiments, catheter systems and associated methods exhibit enhanced capabilities for the deployment and the activation of various transducers, which may be located within a bodily cavity, such as an intracardiac cavity. In some embodiments, systems or a portion thereof may be percutaneously or intravascularly delivered to position the various transducers within the bodily cavity. Various ones of the transducers may be activated to distinguish tissue from blood and may be used to deliver positional information of the device relative to various anatomical features in the bodily cavity, such as the pulmonary veins and mitral valve in an atrium. Various ones of the transducers may employ characteristics such as blood flow detection, impedance change detection or deflection force detection to discriminate between blood and tissue. Various ones of the transducers may be used to treat tissue within a bodily cavity. Treatment may include tissue ablation by way of non-limiting example. Various ones of the transducers may be used to stimulate tissue within the bodily cavity. Stimulation can include pacing by way of non-limiting example. Other advantages will become apparent from the teaching herein to those of skill in the art.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least a part of the shaft receivable in the lumen of the catheter sheath; (iii) a manipulable portion located at least proximate the distal end of the shaft, the manipulable portion including a distal end and sized for delivery through the lumen of the catheter sheath to a bodily cavity located in a body, the distal end of the manipulable portion arranged to be delivered first, with respect to other parts of the manipulable portion, through the lumen of the catheter sheath to the bodily cavity; and (iv) an actuator system operatively coupled to the manipulable portion to vary a shape thereof,

3

the actuator system controlled at least by relative movement between the shaft and the catheter sheath. In various embodiments, the actuator system responds to a first relative movement by varying a shape of at least a part of the manipulable portion extending outside the distal end of the catheter sheath to, at least in part, cause the distal end of the manipulable portion to move along a first trajectory during the first relative movement, the first relative movement being between the catheter sheath and the part of the shaft when a distance between a location on the part of the shaft and a location on the catheter sheath decreases, and the actuator system further responds to a second relative movement by varying a shape of at least the part of the manipulable portion extending outside the distal end of the catheter sheath to, at least in part, cause the distal end of the manipulable portion to move along a second trajectory different than the first trajectory during the second relative movement, the second relative movement being between the catheter sheath and the part of the shaft when a distance between the location on the part of the shaft and the location on the catheter sheath increases.

In some embodiments, (a) the distal end of the manipulable portion follows a coiled path during the first relative movement, (b) the distal end of the manipulable portion follows a coiled path during the second relative movement, or both (a) and (b). In some embodiments, the manipulable portion includes a proximal end and an elongated part extending between the proximal and the distal ends of the manipulable portion, and at least the elongated part of the manipulable portion is coiled after the actuator system varies the shape of at least the part of the manipulable portion extending outside the distal end of the catheter sheath to at least in part cause the distal end of the manipulable portion to move along the first trajectory.

In some embodiments, the manipulable portion may be selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The catheter system may further include a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element being receivable in the lumen of the catheter sheath. The actuator system may be operatively coupled to the control element to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath. The actuator system may be operatively coupled to the control element to cause, when a particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the expanded configuration, at least a portion of the control element to have a first amount of length located outside of the distal end of the catheter sheath. The actuator system may be further operatively coupled to the control element to cause, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the expanded configuration, at least a portion of the control element to have a second amount of length located outside of the distal end of the catheter sheath, the second amount of length being different than the first amount of length. The particular amount of the manipulable portion may be a length of the manipulable portion extend-

4

ing outwardly from the distal end of the catheter sheath to the distal end of the manipulable portion in some embodiments. The control element may include a sleeve and a cable located, at least in part, in a lumen of the sleeve, each of the cable and the sleeve located, at least in part, in a lumen of the shaft. The actuator system may be operatively coupled to the control element in a configuration configured to (c) move the sleeve independently or separately from the cable to cause the sleeve to slide over the cable, and (d) move the cable independently or separately from the sleeve to cause the cable to slide through the lumen of the sleeve.

In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The catheter system may further include a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath. The actuator system may be operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath. The actuator system may be operatively coupled to the control element to cause, when a particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the expanded configuration, at least a portion of the control element to be metered with a first rate, and the actuator system may be operatively coupled to the control element to cause, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the delivery configuration, at least a portion of the control element to be metered with a second rate different than the first rate. In some embodiments, the at least the portion of the control element includes a control cable, and the actuator system is operatively coupled to the control element to cause the control cable to be metered in a direction suitable to reduce an amount of the control cable located outside the distal end of the catheter sheath during one of (e) the transition toward the expanded configuration, and (f) the transition toward the delivery configuration, and to cause the control cable to be metered in a direction suitable to increase an amount of the control cable located outside the distal end of the catheter sheath during the other of (e) and (f).

In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The catheter system may further include a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element being receivable in the lumen of the catheter sheath. The actuator system may be operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is

5

retracted into the distal end of the catheter sheath. The actuator system may be operatively coupled to the control element to cause, when a particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the expanded configuration, the control element to have a first amount of length located outside of the distal end of the catheter sheath. The actuator system may be further operatively coupled to the control element to cause, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the delivery configuration, the control element to have a second amount of length located outside of the distal end of the catheter sheath, the second amount different than the first amount. In some embodiments, the control element includes a sleeve and a cable located, at least in part, in a lumen of the sleeve. In some embodiments, each of the cable and the sleeve may be located, at least in part, in a lumen of the shaft. In some embodiments, the actuator system is operatively coupled to the control element in a configuration configured to (e) move the sleeve independently or separately from the cable to cause the sleeve to slide over the cable, and (f) move the cable independently or separately from the sleeve to cause the cable to slide through the lumen of the sleeve. The particular relative positioning may be a relative longitudinal positioning.

In some embodiments, the elongated portion of the shaft has a length extending between the proximal and the distal ends of the shaft and is sized to position the proximal end of the shaft at a location outside the body when the manipulable portion is located in the bodily cavity. The actuator system may be located at a respective location at least proximate the proximal end of the shaft.

In some embodiments, the manipulable portion may include a plurality of elongate members, each elongate member of the plurality of elongate members including a first end, a second end, and an intermediate portion positioned between the first and the second ends, each intermediate portion including a thickness, a front surface, and a back surface opposite across the thickness from the front surface. The manipulable portion may further include a first portion and a second portion, each of the first and the second portions of the manipulable portion including a respective part of each of at least some of the plurality of elongate members. The manipulable portion may be selectively moveable between: a delivery configuration in which the manipulable portion is sized for delivery through the lumen of the catheter sheath, at least the respective intermediate portions of the elongate members of the plurality of elongate members arranged front surface-toward-back surface in a stacked array when the manipulable portion is in the delivery configuration; and a deployed configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath, the first portion of the manipulable portion forming a first domed shape and the second portion of the manipulable portion forming a second domed shape when the manipulable portion is in the deployed configuration.

In some embodiments, the manipulable portion includes a first portion and a second portion, and the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized for delivery through the lumen of the catheter sheath and a deployed configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The first portion of the manipulable portion may form a first

6

domed shape and the second portion of the manipulable portion may form a second domed shape when the manipulable portion is in the deployed configuration. The first and the second portions of the manipulable portion may be arranged in a clam shell configuration when the manipulable portion is in the deployed configuration. The manipulable portion may be arranged to be delivered second portion first through the lumen of the catheter sheath when delivered in the delivery configuration.

The manipulable portion may include a set of one or more transducers. The catheter sheath, the part of the shaft receivable in the lumen of the catheter sheath, or each of the catheter sheath and the part of the shaft receivable in the lumen of the catheter sheath may include a bendable portion that is bendable during a respective delivery to the bodily cavity. The catheter system may further include a control system operatively coupled to the actuator system, the control system operable to control activation of one or more actuators of the actuator system. The control system may be operable to control activation of the one or more actuators of the actuator system in response to the relative movement between the shaft and the catheter sheath.

In some embodiments, the distal end of the manipulable portion may be located outside of the distal end of the catheter sheath at a first location when a particular spatial relationship exists between the shaft and the catheter sheath during the first relative movement. The distal end of the manipulable portion may be located outside of the distal end of the catheter sheath at a second location when the particular spatial relationship exists between the shaft and the catheter sheath during the second relative movement. In various embodiments, the second location may be different than the first location. In various embodiments, the particular spatial relationship may be a spatial relationship between a third location on the shaft and fourth location on the catheter sheath.

In some embodiments, the first relative movement may cause an increase in an amount of the at least a part of the manipulable portion extending outside the distal end of the catheter sheath, and the second relative movement may cause a decrease in an amount of the at least a part of the manipulable portion extending outside the distal end of the catheter sheath.

In some embodiments, the catheter system may further include a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath. The actuator system may be operatively coupled to the control element to vary a shape of at least the part of the manipulable portion extending outside the distal end of the catheter sheath to, at least in part, cause the distal end of the manipulable portion to move along the first trajectory during the first relative movement. The first trajectory may be a modified trajectory following a respective path along which the distal end of the manipulable portion moves during the first relative movement as compared to a respective trajectory along which the distal end of the manipulable portion would move during the first relative movement absent the control element. In some embodiments, the actuator system may respond to the first relative movement by varying a radius of curvature of a surface of the at least a part of the manipulable portion extending outside the distal end of the catheter sheath to decrease and then subsequently increase during the first relative movement.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system includes: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least a part of the shaft receivable in the lumen of the catheter sheath; and (iii) a manipulable portion located at least proximate the distal end of the shaft, the manipulable portion including a distal end and sized for delivery through the lumen of the catheter sheath, the distal end of the manipulable portion arranged to be delivered first, with respect to other parts of the manipulable portion, through the lumen of the catheter sheath from the proximal end of the catheter sheath toward the distal end of the catheter sheath. A method of the controlling the catheter system may be summarized as including responding to a first relative movement, which causes a distance between a location on the part of the shaft and a location on the catheter sheath to decrease, to vary a shape of at least a part of the manipulable portion extending outside the distal end of the catheter sheath to, at least in part, cause the distal end of the manipulable portion to move along a first trajectory during the first relative movement, and responding to a second relative movement, which causes a distance between the location on the part of the shaft and the location on the catheter sheath to increase, to vary a shape of at least a part of the manipulable portion extending outside the distal end of the catheter sheath to, at least in part, cause the distal end of the manipulable portion to move along a second trajectory during the second relative movement, the second trajectory being different than the first trajectory.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending within the catheter sheath between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft member including a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath to a bodily cavity located in a body, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath toward the bodily cavity prior to at least the elongated portion of the shaft; (iii) a manipulable portion located at least proximate the distal end of the shaft, the manipulable portion sized for delivery through the lumen of the catheter sheath to the bodily cavity; (iv) a projection including a length and extending from a location at least proximate a first one of the proximal end of the catheter sheath and the proximal end of the shaft; (v) a receiver provided at a location at least proximate a second one of the proximal end of the catheter sheath and the proximal end of the shaft, the projection and the receiver configured to matingly engage at least when the part of the shaft is received in the lumen of the catheter sheath; and (vi) an actuator system operatively coupled to the manipulable portion to transmit force to the manipulable portion, the actuator system responsive to varying amounts of the length of the projection being within the receiver by varying the force transmitted to the manipulable portion.

In some embodiments, the projection may extend beyond the first one of the proximal end of the catheter sheath and the proximal end of the shaft at least when the part of the shaft is received in the lumen of the catheter sheath. In some

proximal end of the shaft toward one of the proximal end of the catheter sheath and the proximal end of the shaft other than the first one, at least when the part of the shaft is received in the lumen of the catheter sheath.

In some embodiments, the manipulable portion is configured to not be inserted into the receiver when the manipulable portion is delivered through the lumen of the catheter sheath to the bodily cavity.

In some embodiments, the length of the projection is a longitudinal length of the projection extending from the location at least proximate the first one of the proximal end of the catheter sheath and the proximal end of the shaft to an end of the projection, the end of the projection configured to be received first in the receiver, as compared to other parts of the projection, when the projection is inserted into the receiver. In some embodiments, the shaft includes a longitudinal length extending between the proximal and distal ends of the shaft, and the longitudinal length of the shaft is different than the longitudinal length of the projection. In some embodiments, the longitudinal length of the shaft is greater than the longitudinal length of the projection. In some embodiments, a first particular amount of the longitudinal length of the projection is located in the receiver when a second particular amount of the longitudinal length of the shaft is located inside the lumen of the catheter sheath, the first particular amount of the longitudinal length of the projection being less than the second particular amount of the longitudinal length of the shaft.

In some embodiments, the first one of the proximal end of the catheter sheath and the proximal end of the shaft is a same one as the second one of the proximal end of the catheter sheath and the proximal end of the shaft. In some embodiments, the first one of the proximal end of the catheter sheath and the proximal end of the shaft is different than the second one of the proximal end of the catheter sheath and the proximal end of the shaft. In some embodiments, the second one of the proximal end of the catheter sheath and the proximal end of the shaft is the proximal end of the shaft. In some embodiments, the first one of the proximal end of the catheter sheath and the proximal end of the shaft is the proximal end of the catheter sheath.

In some embodiments, the shaft member may further include a housing physically coupled to the shaft at a location at least proximate the second one of the proximal end of the catheter sheath and the proximal end of the shaft, and the receiver is located, at least in part, in the housing. In some embodiments, the actuator system may be located, at least in part, in the housing.

In some embodiments, the receiver may include an internal receiving mechanism sized to matingly receive at least a portion of the projection, and the actuator system may be responsive to a movement of the internal receiving mechanism within the receiver caused by a change in an amount of the length of the projection within the receiver by varying the force transmitted to the manipulable portion. The internal receiving mechanism may include a coupler that physically couples the internal receiving mechanism to at least the portion of the projection when at least the portion of the projection is matingly received in the internal receiving mechanism. In some embodiments, when at least the portion of the projection is physically coupled to the internal receiving mechanism, at least the coupler of the internal receiving mechanism may be configured to move during each of a first relative movement between the projection and the receiver that increases the amount of the length of the projection within the receiver, and a second relative movement between the projection and the receiver that decreases the

amount of the length of the projection within the receiver. In some embodiments, the coupler captively couples the internal receiving mechanism to at least the portion of the projection when at least the portion of the projection is matingly received in the internal receiving mechanism. In some embodiments, the coupler may be configured to physically couple the internal receiving mechanism to at least the portion of the projection when a first relative positioning between the projection and the receiver is established, and the coupler may be further configured to physically decouple the internal receiving mechanism from the projection when a second relative positioning between the projection and the receiver is established, the second relative positioning being different than the first relative positioning. In some embodiments, the coupler self-couples the internal receiving mechanism to at least the portion of the projection when a first relative positioning between the projection and the receiver is established, and the coupler self-decouples the internal receiving mechanism from the projection when a second relative positioning between the projection and the receiver is established, the second relative positioning being different than the first relative positioning.

In some embodiments, the catheter system includes a control cable that operatively couples the actuator system to the manipulable portion, the control cable being receivable in the lumen of the catheter sheath. The actuator system may be configured to meter the control cable to vary an amount of the control cable that extends outwardly from the distal end of the catheter sheath when the part of the shaft is received in the lumen of the catheter sheath, and the actuator system may be responsive to varying amounts of the length of the projection being within the receiver by varying a rate at which the control cable is metered. The actuator system may be configured to meter the control cable to vary an amount of the control cable that extends outwardly from the distal end of the catheter sheath when the part of the shaft is received in the lumen of the catheter sheath, and the actuator system may be responsive to a rate of change in an amount of the length of the projection being within the receiver by varying a rate at which the control cable is metered. In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The actuator system may be operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath. The actuator system may be operatively coupled to the control cable to cause, when a particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the control cable to be metered with a first rate, and the actuator system may be operatively coupled to the control cable to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the control cable to be metered with a second rate different than the first rate.

In various embodiments, the manipulable portion may be selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the lumen of the catheter sheath and an expanded

configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The catheter system may further include a control element that operatively couples the actuator system to the manipulable portion, the control element receivable in the lumen of the catheter sheath. The actuator system may be operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath. The actuator system may be operatively coupled to the control element to cause, when a particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the control element to have a first amount of length located outside of the distal end of the catheter sheath, and the actuator system may be further operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the control element to have a second amount of length located outside of the distal end of the catheter sheath, the first amount of length different than the second amount of length. In some embodiments, the control element includes a sleeve and a cable received in a lumen of the sleeve. Each of the sleeve and the cable may be received in a lumen of the shaft. The actuator system may be operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the cable to have a third amount of length located outside an end of the sleeve, and the actuator system may be operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the cable to have a fourth amount of length located outside the end of the sleeve, the fourth amount of length different than the third amount of length.

In some embodiments, the manipulable portion includes a set of one or more transducers. In some embodiments, the catheter sheath, the part of the shaft receivable in the lumen of the catheter sheath, or each of the catheter sheath and the part of the shaft receivable in the lumen of the catheter sheath may include a bendable portion sufficiently bendable for delivery to the bodily cavity.

In some embodiments, the projection and the receiver are configured to matingly engage at least when a first amount of the part of the shaft is received in the lumen of the catheter sheath, and the projection and the receiver are configured to not matingly engage at least when a second amount of the part of the shaft is received in the lumen of the catheter sheath. The first amount of the part of the shaft may be different than the second amount of the part of the shaft. At least the second amount of the part of the shaft may be a non-zero amount. In some embodiments, the shaft includes a longitudinal length extending between the proximal and distal ends of the shaft, and each of the first amount and the second amount of the part of the shaft may be an amount of the longitudinal length of the shaft.

In some embodiments, the projection and the receiver may be configured to matingly engage at least when the shaft is not received in the lumen of the catheter sheath. In some embodiments, the projection and the receiver may form part of a plunger assembly located on one of the shaft and the catheter sheath.

In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced outwardly first from the distal end of the catheter sheath, as compared to other parts of the manipulable portion. The actuator system may be configured to vary the force transmitted to the manipulable portion while the distal end of the manipulable portion advances outwardly from the distal end of the catheter sheath along an arcuate path. The actuator system may be configured to vary the force transmitted to the manipulable portion while the distal end of the manipulable portion advances outwardly from the distal end of the catheter sheath along a coiled path.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments a catheter system may be summarized as including: (i) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least the distal end of the shaft sized for delivery through a bodily opening leading to a bodily cavity located in a body; (ii) a manipulable portion physically coupled to the shaft and located at least proximate the distal end of the shaft; (iii) an elongated control element physically coupled to the manipulable portion to transmit force to the manipulable portion; and (iv) an actuator operatively coupled to the elongated control element, at least a portion of the actuator moveable in each of a first direction and a second direction different than the first direction, the actuator operable to meter movement of at least a portion of the elongated control element. Movement of at least the portion of the actuator with a particular rate of movement in the first direction causes movement of the elongated control element by metering the portion of the elongated control element with a first rate of movement. Movement of at least the portion of the actuator with the particular rate of movement in the second direction causes movement of the elongated control element by metering the portion of the elongated control element with a second rate of movement. A first ratio of the first rate of movement to the particular rate of movement may be different than a second ratio of the second rate of movement to the particular rate of movement.

In some embodiments, the catheter system may further include a control system housing enclosing at least (a) some of the shaft, (b) some of the elongated control element, (c) some of the actuator, (a) and (b), (b) and (c), (a) and (c), or (a), (b), and (c). Movement of at least the portion of the actuator with the particular rate of movement in the first direction may be with respect to the housing. Movement of at least the portion of the actuator with the particular rate of movement in the second direction may be with respect to the housing. The control system housing may be located at least proximate the proximal end of the shaft. The control system housing may enclose at least the proximal end of the shaft.

In some embodiments, the second direction may be opposite to the first direction. The portion of the actuator may be configured to move along a linear path when moving in the first direction or in the second direction. The portion of the actuator may be configured to move along an arcuate path when moving in the first direction or in the second direction.

In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the bodily opening and an expanded configuration in which the manipulable portion is sized too large for delivery through the bodily opening. The actuator may be operatively coupled to the elongated control element to vary movement of the elongated control element by switching a ratio of (a) a rate

at which the portion of the elongated control element is metered to (b) a rate of movement of at least the portion of the actuator between each ratio of a first set of two or more different predetermined ratios when the manipulable portion transitions from the delivery configuration to the expanded configuration. The actuator may be operatively coupled to the elongated control element to vary movement of the elongated control element by switching the ratio of (a) to (b) between each ratio of a second set of two or more different predetermined ratios when the manipulable portion transitions from the expanded configuration to the delivery configuration. In some embodiments, the first ratio is a member of the first set, and the second ratio is a member of the second set. At least one of the predetermined ratios in the first set may be the same as one of the predetermined ratios in the second set. At least two of the predetermined ratios in the first set may be the same as at least two of the predetermined ratios in the second set.

In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the bodily opening and an expanded configuration in which the manipulable portion is sized too large for delivery through the bodily opening. The actuator may be operatively coupled to the elongated control element to vary movement of the elongated control element by switching a ratio of (a) a rate at which the portion of the elongated control element is metered to (b) a rate of movement of at least the portion of the actuator between each ratio of a first set of two or more different ratios when the manipulable portion transitions from the delivery configuration to the expanded configuration, each ratio in the first set of two or more different ratios having a value corresponding to a respective one of a first set of two or more different predetermined values. The actuator may be operatively coupled to the elongated control element to vary movement of the elongated control element by switching the ratio of (a) to (b) between each ratio of a second set of two or more different ratios when the manipulable portion transitions from the expanded configuration to the delivery configuration, each ratio in the second set of two or more different ratios having a value corresponding to a respective one of a second set of two or more different predetermined values. In some embodiments, the first ratio is a member of the first set of two or more different ratios, and the second ratio is a member of the second set of two or more different ratios. At least one of the ratios in the first set of two or more different ratios may be the same as one of the ratios in the second set of two or more different ratios. At least two of the ratios in the first set of two or more different ratios may be the same as at least two of the ratios in the second set of two or more different ratios.

In some embodiments, the catheter sheath may further include a catheter sheath including a proximal end, a distal end, and a lumen extending within the catheter sheath between the proximal end of the catheter sheath and the distal end of the catheter sheath, the catheter sheath being positionable in the bodily opening. At least part of the shaft may be receivable in the lumen of the catheter sheath. In some embodiments, movement of at least the portion of the actuator in the first direction may be associated with a first relative movement between the catheter sheath and the part of the shaft, when the part of the shaft is received in the lumen of the catheter sheath, that causes a distance between a location on the part of the shaft and a location on the catheter sheath to decrease. In some embodiments, movement of at least the portion of the actuator in the second direction may be associated with a second relative move-

13

ment between the catheter sheath and the part of the shaft, when the part of the shaft is received in the lumen of the catheter sheath, that causes a distance between the location on the part of the shaft and the location on the catheter sheath to increase.

In some embodiments, the catheter system may further include a projection including a length and extending from a location at least proximate a first one of the proximal end of the catheter sheath and the proximal end of the shaft and a receiver provided at a location at least proximate a second one of the proximal end of the catheter sheath and the proximal end of the shaft, the projection and the receiver configured to matingly engage at least when the part of the shaft is received in the lumen of the catheter sheath. Movement of at least the portion of the actuator in the first direction may be associated with an amount of the length of the projection within the receiver increasing in magnitude, and movement of at least the portion of the actuator in the second direction may be associated with an amount of the length of the projection within the receiver decreasing in magnitude. In some embodiments, the length of the projection is a longitudinal length of the projection extending from the location at least proximate the first one of the proximal end of the catheter sheath and the proximal end of the shaft to an end of the projection, the end of the projection configured to be received first in the receiver, as compared to other parts of the projection, when the projection is inserted into the receiver. In some embodiments, the shaft includes a longitudinal length extending between the proximal and distal ends of the shaft. The longitudinal length of the shaft may be greater than the longitudinal length of the projection in some embodiments. In some embodiments, a first particular amount of the longitudinal length of the projection may be located in the receiver when a second particular amount of the longitudinal length of the shaft is located inside the lumen of the catheter sheath. The first particular amount of the longitudinal length of the projection may be less than the second particular amount of the longitudinal length of the shaft.

In some embodiments, the manipulable portion may be selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the bodily opening and an expanded configuration in which the manipulable portion is sized too large for delivery through the bodily opening. Movement of at least the portion of the actuator in the first direction may transition the manipulable portion, at least in part, toward the expanded configuration, and movement of at least the portion of the actuator in the second direction may transition the manipulable portion, at least in part, toward the delivery configuration.

In some embodiments, the catheter system may further include a catheter sheath including a proximal end, a distal end, and a lumen extending within the catheter sheath between the proximal end of the catheter sheath and the distal end of the catheter sheath, the catheter sheath being positionable in the bodily opening. At least part of the shaft may be receivable in the lumen of the catheter sheath. Movement of at least the portion of the actuator in the first direction may accompany an increase in an amount of the manipulable portion extending outwardly from the distal end of the catheter sheath, and movement of at least the portion of the actuator in the second direction may accompany a decrease in an amount of the manipulable portion extending outwardly from the distal end of the catheter sheath. At least some of the elongated control element may be receivable in the lumen of the catheter sheath, and the actuator may be

14

operatively coupled to the elongated control element to cause an increase and subsequent decrease in an amount of length of the elongated control element that is located outside of the distal end of the catheter sheath when at least the portion of the actuator moves in the first direction. The actuator may be operatively coupled to the elongated control element to cause an increase and subsequent decrease in an amount of length of the elongated control element that is located outside of the distal end of the catheter sheath when at least the portion of the actuator moves in the second direction.

In some embodiments, the elongated control element includes a sleeve and a cable located, at least in part, in a lumen of the sleeve. Each of the cable and the sleeve may be located, at least in part, in a lumen of the shaft. The portion of the elongated control element may be provided by a portion of the cable. In some embodiments, the catheter system may further include a Bowden cable that includes a sleeve and a cable located, at least in part, in a lumen of the sleeve. The portion of the elongated control element may be provided by a portion of the cable.

In some embodiments, the movement of at least the portion of the actuator with the particular rate of movement in the first direction may cause the movement of the elongated control element by metering the portion of the elongated control element with the first rate of movement when the portion of the elongated control element is positioned at a particular location, and the movement of at least the portion of the actuator with the particular rate of movement in the second direction may cause the movement of the elongated control element by metering the portion of the elongated control element with the second rate of movement when the portion of the elongated control element is positioned at the particular location.

The portion of the elongated control element may be moveable along a path during the metering of the portion of the elongated control element. The movement of at least the portion of the actuator with the particular rate of movement in the first direction may cause the portion of the elongated control element to be metered with the first rate of movement and to move in a particular direction away from a particular location along the path. The movement of at least the portion of the actuator with the particular rate of movement in the second direction may cause the portion of the elongated control element to be metered with the second rate of movement and to move in a different direction away from the particular location along the path, the different direction being different than the particular direction.

In various embodiments, the manipulable portion includes a set of one or more transducers. The shaft may be sufficiently bendable for delivery to the bodily cavity in some embodiments. The manipulable portion is physically coupled to the shaft in some embodiments.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system may be summarized as including: (i) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least the distal end of the shaft sized for delivery through a bodily opening leading to a bodily cavity located in a body; (ii) a manipulable portion located at least proximate the distal end of the shaft, the manipulable portion selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the bodily opening and an expanded configuration in which the manipulable portion is sized too large for delivery through

15

the bodily opening; (iii) an elongated control element; and (iv) a control system configured to cause movement of a portion of the elongated control element along a path extending toward the manipulable portion. The control system may be configured, when a portion of the elongated control element is located at a particular position along the path, to meter movement of: (a) the portion of the elongated control element at a first rate in a first direction along the path away from the particular position at least in response to occurrence of a first state that triggers a transition of the manipulable portion toward the expanded configuration, and (b) the portion of the control element at a second rate in a second direction along the path away from the particular position at least in response to occurrence of a second state that triggers a transition of the manipulable portion toward the delivery configuration. The second direction along the path may be different than the first direction along the path, and the second rate may be different than the first rate.

In some embodiments, a catheter system may be summarized as including (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and at least the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion physically coupled to the shaft and located at least proximate the distal end of the shaft, the manipulable portion configurable in a delivery configuration in which the manipulable portion is shaped for delivery through the lumen of the catheter sheath; (iv) a control element receivable in the lumen of the catheter sheath and physically coupled to the manipulable portion to transmit force to the manipulable portion; and (v) an actuator operatively coupled to the control element, at least a portion of the actuator moveable at least in one particular direction to manipulate at least a portion of the control element. Movement of at least the portion of the actuator in the one particular direction may facilitate or cause a length of a part of the control element extending outside the distal end of the catheter sheath to increase and then subsequently decrease during the movement of at least the portion of the actuator in the one particular direction. A part of the manipulable portion may extend outside the distal end of the catheter sheath and have a size too large to fit in the lumen of the catheter sheath during the movement of at least the portion of the actuator in the one particular direction.

In some embodiments, the catheter system may further include a control system housing enclosing at least (a) some of the shaft, (b) some of the control element, (c) some of the actuator, (a) and (b), (b) and (c), (a) and (c), or (a), (b), and (c). Movement of at least the portion of the actuator in the one particular direction may be with respect to the control system housing. The control system housing may be located at least proximate the proximal end of the shaft. The control system housing may enclose at least the proximal end of the shaft.

In some embodiments, the one particular direction is a first direction, and at least the portion of the actuator is selectively moveable in each of the first direction and a second direction to manipulate at least the portion of the control element, the second direction being different than the first direction. Movement of at least the portion of the actuator in the second direction may cause a length of the

16

part of the control element extending outside the distal end of the catheter sheath to increase and then subsequently decrease during the movement of at least the portion of the actuator in the second direction. The part of the manipulable portion may have a size too large to fit in the lumen of the catheter sheath during the movement of at least the portion of the actuator in the second direction. The catheter system may further include a control system housing enclosing at least (a) some of the shaft, (b) some of the control element, (c) some of the actuator, (a) and (b), (b) and (c), (a) and (c), or (a), (b), and (c). Movement of at least the portion of the actuator in each of the first direction and the second direction may be with respect to the control system housing.

In some embodiments, the actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during an advancement of the manipulable portion outwardly from the distal end of the catheter sheath. In some embodiments, the actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during a retraction of the manipulable portion inwardly into the distal end of the catheter sheath. In some embodiments, the actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during a relative longitudinal movement between the shaft and the catheter sheath when the part of the shaft is located in the lumen of the catheter sheath.

In some embodiments, the manipulable portion is selectively moveable between the delivery configuration and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during a transition of the manipulable portion toward the expanded configuration. The actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during a transition of the manipulable portion toward the delivery configuration.

In some embodiments, the movement of at least the portion of the actuator may be associated with a relative movement between the shaft and the catheter sheath, when the part of the shaft is located in the lumen of the catheter sheath.

In some embodiments, the catheter system may further include a modulation actuator operatively coupled to the manipulable portion. The manipulable portion may be selectively moveable between the delivery configuration and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The modulation actuator may be configured to modulate at least a size, a shape, or both a size and a shape of at least the part of the manipulable portion at least when the manipulable portion transitions between the delivery configuration and the expanded configuration in a state in

17

which at least the part of the manipulable portion and the part of the control element extend outside the distal end of the catheter sheath. The actuator may be operatively coupled to the control element to cause, when a particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during a transition toward the expanded configuration, at least a first portion of the control element to be metered with a first rate. The actuator may be further operatively coupled to the control element to cause, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during a transition toward the delivery configuration, at least a second portion of the control element to be metered with a second rate different than the first rate. The manipulable portion may be configured to transition, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath. The manipulable portion may be configured to transition, at least in part, toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

In some embodiments, the catheter system may further include a modulation actuator operatively coupled to the manipulable portion. The manipulable portion may be selectively moveable between the delivery configuration and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. The modulation actuator may be configured to facilitate modulation of at least a size, a shape, or both a size and a shape of at least the part of the manipulable portion at least when the manipulable portion transitions between the delivery configuration and the expanded configuration in a state in which at least the part of the manipulable portion and the part of the control element extend outside the distal end of the catheter sheath. The actuator may be operatively coupled to the control element to cause, when a particular relative positioning exists between the catheter sheath and the part of the shaft located in the lumen of the catheter sheath during a transition toward the expanded configuration, the control element to have a first amount of length located outside of the distal end of the catheter sheath. The actuator may be operatively coupled to the control element to cause, when the particular relative positioning exists between the catheter sheath and the part of the shaft located in the lumen of the catheter sheath during a transition toward the delivery configuration, the control element to have a second amount of length located outside of the distal end of the catheter sheath, the second amount of length different than the first amount of length. The manipulable portion may be configured to transition, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath. The manipulable portion may be configured to transition, at least in part, toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath. The particular relative positioning may be a relative longitudinal positioning. In some embodiments, the control element may include a sleeve and a cable located, at least in part, in a lumen of the sleeve. The actuator may be operatively coupled to the control element to cause, when the particular relative positioning exists between the catheter sheath and the part of the shaft located in the lumen of the catheter sheath during the transition toward the expanded configuration, the cable to have a third amount of length located outside of an end of the sleeve. The actuator may be operatively coupled to the control element to cause, when the particular relative positioning exists between the catheter

18

sheath and the part of the shaft located in the lumen of the catheter sheath during the transition toward the delivery configuration, the cable to have a fourth amount of length located outside of the end of the sleeve, the fourth amount of length different than the third amount of length.

In some embodiments, the control element may include a sleeve and a cable located, at least in part, in a lumen of the sleeve, each of the cable and the sleeve located, at least in part, in a lumen of the shaft.

In some embodiments, the elongated portion of the shaft has a length extending between the proximal and the distal ends of the shaft and is sized to position the proximal end of the shaft at a location outside a body when the manipulable portion is located in a bodily cavity within the body. The actuator may be located, at least in part, at a location at least proximate the proximal end of the shaft.

In some embodiments, the manipulable portion includes a set of one or more transducers. In some embodiments, the shaft, the catheter sheath, or each of the shaft and the catheter sheath is bendable during a respective delivery to a bodily cavity.

In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced first outwardly from the distal end of the catheter sheath with respect to other parts of the manipulable portion. The actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and then subsequently decrease during the movement of at least the portion of the actuator in the one particular direction while the distal end of the manipulable portion advances along an arcuate path extending outwardly from the distal end of the catheter sheath. The actuator may be operatively coupled to the control element to manipulate at least the portion of the control element to cause the length of the part of the control element extending outside the distal end of the catheter sheath to increase and then subsequently decrease during the movement of at least the portion of the actuator in the one particular direction while the distal end of the manipulable portion advances along a coiled path extending outwardly from the distal end of the catheter sheath.

In some embodiments, the catheter system may further include a modulation actuator operatively coupled to the manipulable portion to modulate at least a size, a shape, or both a size and a shape of at least the part of the manipulable portion at least in a state in which at least the part of the manipulable portion and the part of the control element extend outside the distal end of the catheter sheath. In some embodiments, the actuator includes the modulation actuator. In some embodiments, the actuator and the modulation actuator are distinct.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion physically coupled to the shaft and located at

least proximate the distal end of the shaft, the manipulable portion selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath; (iv) a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath; and (v) an actuator system. The actuator system may be operatively coupled to at least the control element to cause at least, when a particular amount of the manipulable portion is located outside the distal end of the catheter sheath, the control element to have a first amount of length located outside of the distal end of the catheter sheath, at least in response to occurrence of a first state that triggers a transition of the manipulable portion toward the expanded configuration. The actuator system may be operatively coupled to at least the control element to cause at least, when the particular amount of the manipulable portion is located outside the distal end of the catheter sheath, the control element to have a second amount of length located outside of the distal end of the catheter sheath, at least in response to occurrence of a second state that triggers a transition of the manipulable portion toward the delivery configuration. The second amount of length may be different than the first amount of length.

In some embodiments, the actuator system may be operatively coupled to the control element to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition the manipulable portion, at least in part, toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

In some embodiments, the control element may include a cable. In some embodiments, the control element may include a sleeve and a cable located, at least in part, in a lumen of the sleeve. Each of the cable and the sleeve may be located in a lumen of the shaft. The actuator system may be operatively coupled to the control element to cause at least, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the expanded configuration, the cable to have a third amount of length located outside an end of the sleeve. The actuator system may be operatively coupled to the control element to cause at least, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the delivery configuration, the cable to have a fourth amount of length located outside the end of the sleeve, the fourth amount of length different than the third amount of length.

In some embodiments, the actuator system may be operatively coupled to the control element to cause at least, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the expanded configuration, at least a portion of the control element to be metered with a first rate. The actuator system may be operatively coupled to the control element to cause at least, when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath during the transition toward the delivery configuration, at least the portion of the control element to be metered with a second rate different than the first rate.

The shaft, the catheter sheath, or each of the shaft and the catheter sheath may be bendable during a respective delivery to a bodily cavity. In some embodiments, the manipulable portion may include a coiled form in the expanded configuration. In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced first outwardly from the distal end of the catheter sheath with respect to other parts of the manipulable portion. The distal end of the manipulable portion may advance along an arcuate path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath. The distal end of the manipulable portion may advance along a coiled path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath.

In some embodiments, the control element includes a distal end positionable outside of the distal end of the catheter sheath when the particular amount of the manipulable portion is located outside of the distal end of the catheter sheath. The distal end of the control element may advance along a coiled path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath.

In some embodiments, the actuator system may include a transition actuator operatively coupled to the manipulable portion to transition the manipulable portion at least partially between the expanded configuration and the delivery configuration.

In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced first outwardly from the distal end of the catheter sheath with respect to other parts of the manipulable portion. In some embodiments, the particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular size of the manipulable portion between the distal end of the catheter sheath and the distal end of the manipulable portion. In some embodiments, the particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular length of the manipulable portion extending from the distal end of the catheter sheath to the distal end of the manipulable portion. In some embodiments, the particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular length of the manipulable portion extending along a surface of the manipulable portion from the distal end of the catheter sheath to the distal end of the manipulable portion. The manipulable portion may include at least one transducer located on the surface of the manipulable portion.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion physically coupled to the shaft and located at least proximate the distal end of the shaft, the manipulable portion selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an

21

expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath; (iv) a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath; and (v) an actuator system. The actuator system may be operatively coupled to at least the control element to cause at least, when a particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during a transition of the manipulable portion toward the expanded configuration, the control element to have a first amount of length located outside of the distal end of the catheter sheath, at least in response to occurrence of a first state that triggers a transition of the manipulable portion toward the expanded configuration. The actuator system may be operatively coupled to at least the control element to cause at least, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during a transition of the manipulable portion toward the delivery configuration, the control element to have a second amount of length located outside of the distal end of the catheter sheath, at least in response to occurrence of a second state that triggers a transition of the manipulable portion toward the delivery configuration. The second amount of length may be different than the first amount of length in various embodiments.

In some embodiments, the particular relative positioning may be a relative longitudinal positioning. In some embodiments, the actuator system may be operatively coupled to the control element to transition the manipulable portion toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

In some embodiments, the control element includes a cable. In some embodiments, the control element is received in a lumen of the shaft. In some embodiments, the control element includes a sleeve and a cable located, at least in part, in a lumen of the sleeve. The actuator system may be operatively coupled to the control element to cause at least, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the expanded configuration, the cable to have a third amount of length located outside of an end of the sleeve. The actuator system may be operatively coupled to the control element to cause at least, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the delivery configuration, the cable to have a fourth amount of length located outside of the end of the sleeve, the fourth amount of length different than the third amount of length.

In some embodiments, the actuator system may be operatively coupled to the control element to cause at least, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the expanded configuration, at least a portion of the control element to be metered with a first rate. The actuator system may be operatively coupled to the control element to cause at least, when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the delivery configuration, at least the portion of the control element to be metered with a second rate different than the first rate.

22

In some embodiments, the manipulable portion may include a set of one or more transducers. The shaft, the catheter sheath, or each of the shaft and the catheter sheath may be bendable during a respective delivery to a bodily cavity.

In some embodiments, the manipulable portion may include a coiled form in the expanded configuration. In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced first outwardly from the distal end of the catheter sheath with respect to other parts of the manipulable portion. In some embodiments, the distal end of the manipulable portion advances along an arcuate path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath. In some embodiments, the distal end of the manipulable portion advances along a coiled path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath. In some embodiments, the control element includes a distal end, the distal end of the control element advancing along a coiled path as the manipulable portion is advanced outwardly from the distal end of the catheter sheath. In some embodiments, the actuator system may include a transition actuator operatively coupled to the manipulable portion to transition the manipulable portion at least partially between the expanded configuration and the delivery configuration.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion physically coupled to the shaft and located at least proximate the distal end of the shaft, the manipulable portion configurable in a delivery configuration in which the manipulable portion is shaped for delivery through the lumen of the catheter sheath; and (iv) a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath. A method for controlling the catheter system may be summarized as modulating at least a shape of at least part of the manipulable portion at least in a state in which the part of the manipulable portion and a part of the control element extends outside the distal end of the catheter sheath, and manipulating the control element to cause a length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during the modulation of the manipulable portion. The manipulable portion may have a size during the modulation too large to fit in the lumen of the catheter sheath.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged

to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion physically coupled to the shaft and located at least proximate the distal end of the shaft, the manipulable portion selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath; and (iv) a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath. A method for controlling the catheter system may be summarized as including transitioning the manipulable portion at least partially between the expanded configuration and the delivery configuration; causing the control element to have a first amount of length located outside of the distal end of the catheter sheath when a particular amount of the manipulable portion is located outside the distal end of the catheter sheath during a transition toward the expanded configuration; and causing the control element to have a second amount of length located outside of the distal end of the catheter sheath, when the particular amount of the manipulable portion is located outside the distal end of the catheter sheath during a transition toward the delivery configuration. The second amount of length may be different than the first amount of length in various embodiments.

The method may further include transitioning the manipulable portion toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and transitioning the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

In some embodiments, the manipulable portion includes a distal end, the distal end of the manipulable portion arranged to be advanced first outwardly from the distal end of the catheter sheath with respect to other parts of the manipulable portion. The particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular size of the manipulable portion between the distal end of the catheter sheath and the distal end of the manipulable portion. The particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular length of the manipulable portion extending from the distal end of the catheter sheath to the distal end of the manipulable portion. The particular amount of the manipulable portion located outside the distal end of the catheter sheath may be a particular length of the manipulable portion extending along a surface of the manipulable portion from the distal end of the catheter sheath to the distal end of the manipulable portion. The manipulable portion may include at least one transducer located on the surface of the manipulable portion.

Various methods may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system may be summarized as including: (i) a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath; (ii) a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft; (iii) a manipulable portion coupled to the shaft and located at least

proximate the distal end of the shaft, the manipulable portion selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath; and (iv) a control element physically coupled to the manipulable portion to transmit force to the manipulable portion, the control element receivable in the lumen of the catheter sheath. A method for controlling the catheter system may be summarized as including transitioning the manipulable portion at least partially between the expanded configuration and the delivery configuration; causing the control element to have a first amount of length located outside of the distal end of the catheter sheath when a particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the expanded configuration; and causing the control element to have a second amount of length located outside of the distal end of the catheter sheath when the particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward the delivery configuration. The second amount of length may be different than the first amount of length in various embodiments.

In some embodiments, the method further includes transitioning the manipulable portion toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and transitioning the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

In some embodiments, a catheter system may be summarized as including (i) a shaft member that includes a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end and the distal end, wherein at least the distal end of the shaft is sized for delivery through a bodily opening leading to a bodily cavity located in a body; (ii) a manipulable portion physically coupled to the shaft and located at least proximate to the distal end of the shaft for delivery through the bodily opening to the bodily cavity located in the body; (iii) a plurality of Bowden cables, at least a part of one of which is operatively coupled to the manipulable portion, the plurality of Bowden cables including at least a first Bowden cable and a second Bowden cable other than the first Bowden cable, each of the plurality of Bowden cables including a respective sleeve and a respective cable located in a lumen of the respective sleeve, the lumen extending between a first end and a second end of the respective sleeve, and a first part of the respective cable of each Bowden cable extending outwardly from the first end of the respective sleeve of the Bowden cable; and (iv) an actuator system operatively coupled to each of at least some of the plurality of Bowden cables to vary an amount of length of the first part of the respective cable of each of the at least some of the plurality of Bowden cables that extends outwardly from the first end of the respective sleeve thereof during a change in a size, a shape, or both a size and a shape of the manipulable portion. The first part of the respective cable of the second Bowden cable may be operatively coupled to the first Bowden cable to cause at least the first end of the respective sleeve of the first Bowden cable to translate in response to a varying of the amount of length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable caused by the actuator system.

25

In some embodiments, the actuator system may be operatively coupled to the first Bowden cable to cause a decrease in the length of the first part of the respective cable of the first Bowden cable during at least part of the varying of the length of the first part of the respective cable of the second Bowden cable. In some embodiments, the actuator system may be operatively coupled to the first Bowden cable to cause an increase in the length of the first part of the respective cable of the first Bowden cable that extends outwardly from the first end of the respective sleeve of the first Bowden cable during at least part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable. In some embodiments, the actuator system may be operatively coupled to the second Bowden cable to translate the second end of the respective sleeve of the second Bowden cable during at least part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

In some embodiments, a second part of the respective cable of each Bowden cable extends outwardly from the second end of the respective sleeve of the Bowden cable. In some embodiments, an amount of translation undergone by a terminus of the second part of the respective cable of the second Bowden cable at a particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable may have a magnitude less than an amount of translation undergone by the second end of the respective sleeve of the second Bowden cable at the particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

In some embodiments, the actuator system may be operatively coupled to the second Bowden cable to translate the second end of the respective sleeve of the first Bowden cable during at least part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable. In some embodiments, the actuator system may be operatively coupled to the second Bowden cable to translate each of the second end of the respective sleeve of the second Bowden cable and the second end of the respective sleeve of the first Bowden cable during at least part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

In some embodiments, the actuator system, in a state in which the first end of the respective sleeve of the first Bowden cable has translated by a predetermined amount, may cause: (v) the first Bowden cable to vary the length of the first part of the respective cable of the first Bowden cable that extends outwardly from the first end of the respective sleeve of the first Bowden cable; and (vi) the second Bowden cable to cease varying the length of the first part of the respective cable of the second Bowden cable during a varying of the length of the first part of the respective cable of the first Bowden cable that extends outwardly from the first end of the respective sleeve of the first Bowden cable after at least the first end of the respective sleeve of the first Bowden cable has translated by the predetermined amount. In some embodiments, in the state in which the first end of

26

the respective sleeve of the first Bowden cable has translated by the predetermined amount, the actuator system may cause at least the second end of the respective sleeve of the second Bowden cable to translate during the varying of the length of the first part of the respective cable of the first Bowden cable that extends outwardly from the first end of the respective sleeve of the first Bowden cable after at least the first end of the respective sleeve of the first Bowden cable has translated by the predetermined amount.

In some embodiments, an amount of translation undergone through the lumen of the respective sleeve of the first Bowden cable by a portion of the respective cable of the first Bowden cable at a particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable may be at least equal in magnitude to an amount of translation undergone through the lumen of the respective sleeve of the second Bowden cable by a portion of the respective cable of the second Bowden cable at the particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable. In some embodiments, an amount of translation undergone through the lumen of the respective sleeve of the first Bowden cable by a portion of the respective cable of the first Bowden cable at a particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable may be greater in magnitude than an amount of translation undergone through the lumen of the respective sleeve of the second Bowden cable by a portion of the respective cable of the second Bowden cable at the particular time during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

The shaft member may further include a housing located at a location at least proximate the proximal end of the shaft. In some embodiments, the elongated portion of the shaft may have a length extending between the proximal end and the distal end of the shaft sized to position the housing outside the body when the manipulable portion is located in the bodily cavity, and each of the first end and the second end of the respective sleeve member of the second Bowden cable may be located at a respective location in the housing. In some embodiments, each of the first end and the second end of the respective sleeve member of the first Bowden cable may be located at a respective location in the housing. In some embodiments, the catheter system may further include a stop positioned to restrict at least the first end of the respective sleeve of the first Bowden cable from being translated by more than a maximum amount.

In various embodiments, a second part of the respective cable of each Bowden cable extends outwardly from the second end of the respective sleeve of the Bowden cable. In some embodiments, the actuator system may include a particular actuator including a first moveable portion and a second moveable portion other than the first moveable portion. The second part of the respective cable of the second Bowden cable may be physically coupled to the first moveable portion of the particular actuator. A portion of the respective sleeve of the second Bowden cable located at least proximate to the second end of the respective sleeve of the second Bowden cable may be physically coupled to the second moveable portion of the particular actuator, and the

first moveable portion of the particular actuator may include a locking device configured to restrict movement of the first moveable portion of the particular actuator at least during the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable. In some embodiments, the locking device may be configured to allow movement of the first moveable portion of the particular actuator after completion of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable. In some embodiments, the particular actuator may restrict further varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable during the movement of the first moveable portion of the particular actuator when the locking device is operated to cease restricting movement of the first moveable portion of the particular actuator. In some embodiments, the locking device may be configured to allow movement of the first moveable portion of the particular actuator after the second moveable portion of the particular actuator translates by a defined amount. In some embodiments, the particular actuator may further include a tether, the tether physically coupling the first moveable portion of the particular actuator to the second moveable portion of the particular actuator. The locking device may be configured to restrict movement of the first moveable portion of the particular actuator when a tension in the tether has a magnitude lower than a defined threshold, and the locking device may be configured to allow movement of the first moveable portion of the particular actuator when a tension in the tether has a magnitude greater than the defined threshold.

In some embodiments, the catheter system may further include a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath. The catheter sheath is insertable in the bodily opening and at least a part of the shaft may be receivable in the lumen of the catheter sheath to deliver the manipulable portion through the lumen of the catheter sheath to the bodily cavity. In various embodiments, the actuator system may be responsive to variances in a relative positioning between the shaft and the catheter sheath when the part of the shaft is received in the lumen of the catheter sheath to vary the length of the first part of the respective cable of at least the second Bowden cable that extends from the respective sleeve thereof.

In some embodiments, the catheter system may further include a catheter sheath that includes a proximal end, a distal end, and a lumen extending between the proximal end of the catheter sheath and the distal end of the catheter sheath. In various embodiments, the catheter sheath may be deliverable, distal end first, through the bodily opening toward the bodily cavity and at least a part of the shaft is receivable in the lumen of the catheter sheath to deliver the manipulable portion through the lumen of the catheter sheath to the bodily cavity. In various embodiments, the manipulable portion may be selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath. In some embodiments, the actuator system may cause, when the part of the shaft is received in the lumen of the catheter sheath, and when a

particular relative positioning exists between the catheter sheath and the part of the shaft received in the lumen of the catheter sheath during a transition toward the expanded configuration, the first part of the respective cable of the first Bowden cable to have a first amount of length located outside of the distal end of the catheter sheath. In some embodiments, the actuator system may cause, when the part of the shaft is received in the lumen of the catheter sheath, and when the particular relative positioning exists between the catheter sheath and the part of the shaft received in the lumen of the catheter sheath during a transition toward the delivery configuration, the first part of the respective cable of the first Bowden cable to have a second amount of length located outside of the distal end of the catheter sheath, the second amount of length different than the first amount of length.

In various embodiments, the first part of the respective cable of the first Bowden cable may be physically coupled to the manipulable portion to, at least in part, change the size, the shape, or both a size and a shape of the manipulable portion. For each of at least one of the plurality of Bowden cables, the actuator system may be configured to (a) move the respective sleeve independently or separately from the respective cable to cause the respective sleeve to slide over the respective cable, and (b) move the respective cable independently or separately from the respective sleeve to cause the respective cable to slide through the lumen of the respective sleeve. For the first Bowden cable, the actuator system may be configured to (a) move the respective sleeve independently or separately from the respective cable to cause the respective sleeve to slide over the respective cable, and (b) move the respective cable independently or separately from the respective sleeve to cause the respective cable to slide through the lumen of the respective sleeve.

In some embodiments, the manipulable portion may include a set of one or more transducers. The shaft may include a bendable portion that is bendable during a respective delivery to the bodily cavity.

In some embodiments, the lumen of the respective sleeve of the Bowden cable extends longitudinally in a particular direction from the first end of the respective sleeve of the first Bowden cable, and the first part of the respective cable of the second Bowden cable may be operatively coupled to the first Bowden cable to cause at least the first end of the respective sleeve of the first Bowden cable to translate in a direction having a component parallel to the particular direction at least during part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

In some embodiments, the first part of the respective cable of the second Bowden cable may be operatively coupled to the first Bowden cable to cause at least the first end of the respective sleeve of the first Bowden cable to translate in a direction that causes the length of the first part of the respective cable of the first Bowden cable to vary at least during part of the varying of the length of the first part of the respective cable of the second Bowden cable that extends outwardly from the first end of the respective sleeve of the second Bowden cable.

In some embodiments, the catheter system may further include a control system operatively coupled to the actuator system and operable to control activation of one or more actuators of the actuator system to vary the amount of length of the first part of the respective cable of each of the at least some of the plurality of Bowden cables that extends outwardly from the first end of the respective sleeve thereof

29

during the change in the size, the shape, or both a size and a shape of the manipulable portion.

Various systems may include combinations and subsets of all the systems summarized above.

In some embodiments, a catheter system may be summarized as including: (i) a shaft member that includes a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end and the distal end, wherein at least the distal end of the shaft is sized for delivery through a bodily opening leading to a bodily cavity located in a body; (ii) a manipulable portion physically coupled to the shaft and located at least proximate to the distal end of the shaft for delivery through the bodily opening to the bodily cavity located in the body; (iii) a Bowden cable that includes a sleeve and a cable located in a lumen of the sleeve, the lumen extending between a first end and a second end of the respective sleeve; and (iv) an actuator system operatively coupled to the Bowden cable to (a) move the sleeve independently or separately from the cable to cause the sleeve to slide over the cable during a first manipulation of the manipulable portion to change, a size, a shape or both thereof, and (b) move the cable independently or separately from the sleeve to cause the cable to slide through the lumen of the sleeve during a second manipulation of the manipulable portion to change, a size, a shape or both thereof.

Various systems may include combinations and subsets of all the systems summarized above or otherwise described herein.

Various methods may include combinations and subsets of all the methods summarized above or otherwise described herein.

In some embodiments, some or all of any of the systems or devices summarized above or otherwise described herein, or one or more combinations thereof, may be controlled by one or more control methods for executing some or all of the functionality of such systems or devices summarized above or otherwise described herein. In some embodiments, a computer program product may be provided that comprises program code portions for performing some or all of any of such control methods, when the computer program product is executed by a computing device. The computer program product may be stored on one or more computer-readable storage mediums. In some embodiments, each of the one or more computer-readable storage mediums is a non-transitory computer-readable storage medium. In some embodiments, such control methods are implemented or executed in part or in whole by at least one data processing device or system upon configuration thereof by one or more programs executable by the at least one data processing device or system and stored in one or more computer-readable storage mediums. In some embodiments, each of the one or more computer-readable storage mediums is a non-transitory computer-readable storage medium.

BRIEF DESCRIPTION OF THE DRAWINGS

It is to be understood that the attached drawings are for purposes of illustrating aspects of various embodiments and may include elements that are not to scale.

FIG. 1 is a schematic representation of a system, according to some example embodiments, the system including a data processing device system, an input-output device system, and a processor-accessible memory device system.

30

FIG. 2 is a cutaway diagram of a heart showing a transducer-based device percutaneously placed in a left atrium of the heart, according to some example embodiments.

FIG. 3A is a partially schematic representation of a catheter system, according to some example embodiments, the system, which may also be referred to as a medical system, including a data processing device system, an input-output device system, a processor-accessible memory device system, and a manipulable portion shown in a delivery or unexpanded configuration.

FIG. 3B is the catheter system of FIG. 3A with the manipulable portion shown in a deployed or expanded configuration, according to some example embodiments.

FIG. 4 is a schematic representation of a transducer-based device that includes a flexible circuit structure, according to some example embodiments.

FIG. 5A is a perspective representation of a catheter system, according to some example embodiments.

FIG. 5B is a perspective view of an elongate member of a structure provided by a manipulable portion of the catheter system of FIG. 5A, according to some example embodiments.

FIG. 5C is a perspective view of a manipulable portion of the catheter system of FIG. 5A, the manipulable portion in an initial or predisposed configuration, according to some example embodiments.

FIGS. 5D, 5E, and 5F are various side elevation views of a positioning of a shaft into a catheter sheath at three successive points in time, each of the shaft and the catheter sheath provided by the catheter system of FIG. 5A, according to some example embodiments.

FIG. 5G is a perspective view of a manipulable portion of the catheter system of FIG. 5A, the manipulable portion in a delivery configuration, according to some example embodiments.

FIGS. 5H, 5I, and 5J are various side elevation views of various respective parts of a manipulable portion positioned at three successive points in time as a part of the manipulable portion is advanced outwardly from the confines of a lumen of a catheter sheath, according to some example embodiments, each of the manipulable portion and the catheter sheath provided by the catheter system of FIG. 5A, according to some example embodiments.

FIG. 5K is a side elevation view of a retraction of a manipulable portion to a particular location relative to a catheter sheath, each of the manipulable portion and the catheter sheath provided by the catheter system of FIG. 5A, according to some example embodiments.

FIG. 5L-1 is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as a first fanned configuration, according to some example embodiments.

FIG. 5L-2 is a top plan view of the manipulable portion configured in the first fanned configuration of FIG. 5L-1, according to some example embodiments.

FIG. 5M-1 is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as a second fanned configuration, according to some example embodiments.

FIG. 5M-2 is a top plan view of the manipulable portion configured in the second fanned configuration of FIG. 5M-1, according to some example embodiments.

FIG. 5N is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as enlarged expanded configuration, according to some example embodiments.

31

FIG. 5O is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as a flattened expanded configuration, according to some example embodiments.

FIG. 5P is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as an open clam shell configuration, according to some example embodiments.

FIG. 5Q is a perspective view of a manipulable portion of the catheter system of FIG. 5A configured in an expanded configuration known as a closed clam shell configuration, according to some example embodiments.

FIGS. 5R-1 and 5R-2 are respective top and bottom perspective views of a portion of the catheter system of FIG. 5A with various external portions of a housing thereof removed, according to some example embodiments.

Each of FIGS. 5R-3 and 5R-4 represents a detailed view of a respective one of an engagement and disengagement between various parts of the catheter system of FIG. 5A, according to some example embodiments.

FIGS. 5S-1, 5S-2, 5S-3, 5S-4, 5S-5, and 5S-6 are top plan views of a number of actuators affiliated with a handle portion of the catheter system of FIG. 5A, various ones of the actuators positioned in respective activation positions, according to some example embodiments.

FIGS. 5T, 5U, and 5V are various side elevation views of a positioning of a shaft into a catheter sheath at three successive points in time, according to some example embodiments.

FIGS. 5W-1, 5W-2, 5W-3, and 5W-4 each respectively show plan and elevation views of a portion of a catheter system, according to some embodiments.

FIG. 6 is a graph that includes various lines representative of a metering of a control element during a take-up thereof and a play-out thereof, according to some example embodiments.

FIGS. 7A and 7B are schematic representations of least one actuator at two successive points in time as employed in some example embodiments.

FIGS. 8A and 8B are schematic views of a locking device at two successive points in time as employed in some example embodiments.

FIG. 9A is a flow chart representing a method for controlling a catheter system, according to some example embodiments.

FIG. 9B is a flow chart representing a method for controlling a catheter system, according to some example embodiments.

FIG. 9C is an exploded view of one of the blocks in the flow chart of FIG. 9B, according to some example embodiments.

FIG. 9D is a flow chart representing a method for controlling a catheter system, according to some example embodiments.

FIG. 9E is a flow chart representing a method for controlling a catheter system, according to some example embodiments.

FIGS. 10A, 10B, 10C, and 10D illustrate a slider locking device, according to some example embodiments.

DETAILED DESCRIPTION

In the following description, certain specific details are set forth in order to provide a thorough understanding of various embodiments of the invention. However, one skilled in the art will understand that the invention may be practiced without one or more of these details. In some instances,

32

well-known structures have not been shown or described in detail to avoid unnecessarily obscuring descriptions of various embodiments of the invention.

Reference throughout this specification to “one embodiment” or “an embodiment” or “an example embodiment” or “an illustrated embodiment” or “a particular embodiment” and the like means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, the appearances of the phrases “in one embodiment” or “in an embodiment” or “in an example embodiment” or “in this illustrated embodiment” or “in this particular embodiment” and the like in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures or characteristics of different embodiments may be combined in any suitable manner to form one or more other embodiments.

Unless otherwise explicitly noted or required by context, the word “or” is used in this disclosure in a non-exclusive sense. In addition, unless otherwise explicitly noted or required by context, the word “set” is intended to mean one or more, and the word “subset” is intended to mean a set having the same or fewer elements of those present in the subset’s parent or superset.

Further, the phrase “at least” is used herein at times merely to emphasize the possibility that other elements may exist besides those explicitly listed. However, unless otherwise explicitly noted (such as by the use of the term “only”) or required by context, non-usage herein of the phrase “at least” nonetheless includes the possibility that other elements may exist besides those explicitly listed. For example, the phrase “based at least upon A” includes A as well as the possibility of one or more other additional elements or functions besides A. In the same manner, the phrase “based upon A” includes A, as well as the possibility of one or more other additional elements or functions besides A. However, the phrase “based only upon A” includes only A. For another similar example, each of the phrases “configured at least to A” and “configured to at least A” includes a configuration to perform A, as well as the possibility of one or more other additional actions besides A. In the same manner, the phrase “configured to A” includes a configuration to perform A, as well as the possibility of one or more other additional actions besides A. However, the phrase “configured only to A”, for example, means a configuration to perform only A.

The word “ablation” as used in this disclosure should be understood to include, for example, any disruption to certain properties of tissue. Most commonly, the disruption is to the electrical conductivity and is achieved by heating, which can be generated with resistive or radio-frequency (RF) techniques for example. However, any other technique for such disruption may be included when the term “ablation” is used, such as mechanical, chemical, or optical techniques.

The word “fluid” as used in this disclosure should be understood to include, for example, any fluid that can be contained within a bodily cavity or can flow into or out of, or both into and out of a bodily cavity via one or more bodily openings positioned in fluid communication with the bodily cavity. In the case of cardiac applications, fluid such as blood will flow into and out of various intra-cardiac cavities (e.g., a left atrium or right atrium).

The words “bodily opening” as used in this disclosure should be understood to include, for example, a naturally occurring bodily opening or channel or lumen; a bodily opening or channel or lumen or perforation formed by an instrument or tool using techniques that can include, but are not limited to, mechanical, thermal, electrical, chemical, and

exposure or illumination techniques; a bodily opening or channel or lumen formed by trauma to a body; or various combinations of one or more of the above. Various elements having respective openings, lumens or channels and positioned within the bodily opening (e.g., a catheter sheath or catheter introducer) may be present in various embodiments. These elements may provide a passageway through a bodily opening for various devices employed in various embodiments.

The words “bodily cavity” as used in this disclosure should be understood to mean a cavity in a body. The bodily cavity may be a cavity provided in a bodily organ (e.g., an intra-cardiac cavity or chamber of a heart). The bodily cavity may be provided by a bodily vessel.

The word “tissue” as used in some embodiments in this disclosure should be understood to include, for example, any surface-forming tissue that is used to form a surface of a body or a surface within a bodily cavity, a surface of an anatomical feature or a surface of a feature associated with a bodily opening positioned in fluid communication with the bodily cavity. The tissue can include, for example, part or all of a tissue wall or membrane that defines a surface of the bodily cavity. In this regard, the tissue can form an interior surface of the cavity that surrounds a fluid within the cavity. In the case of cardiac applications, tissue can include, for example, tissue used to form an interior surface of an intra-cardiac cavity such as a left atrium or right atrium. In some embodiments, tissue is non-excised tissue. In some embodiments, the word tissue can refer to a tissue having fluidic properties (e.g., blood).

The term “transducer” as used in this disclosure should be interpreted broadly as any device capable of distinguishing between fluid and tissue, sensing temperature, creating heat, ablating tissue, measuring electrical activity of a tissue surface, stimulating tissue, or any combination thereof. A transducer can convert input energy of one form into output energy of another form. Without limitation, a transducer can include, for example, an electrode that functions as, or as part of, a sensing device included in the transducer, an energy delivery device included in the transducer, or both a sensing device and an energy delivery device included in the transducer. A transducer may be constructed from several parts, which may be discrete components or may be integrally formed.

The term “activation” as used in this disclosure should be interpreted broadly as making active a particular function as related to various transducers disclosed in this disclosure. Particular functions can include, but are not limited to, tissue ablation, sensing electrophysiological activity, sensing temperature and sensing electrical characteristics (e.g., tissue impedance). For example, in some embodiments, activation of a tissue ablation function of a particular transducer is initiated by causing energy sufficient for tissue ablation from an energy source device system to be delivered to the particular transducer. Alternatively, in this example, the activation can be deemed to be initiated when the particular transducer is activated to cause a temperature sufficient for the tissue ablation due to the energy provided by the energy source device system. Also in this example, the activation can last for a duration of time concluding when the ablation function is no longer active, such as when energy sufficient for the tissue ablation is no longer provided to the particular transducer. Alternatively, in this example, the activation period can be deemed to be concluded when the temperature caused by the particular transducer is below the temperature sufficient for the tissue ablation. In some contexts, however, the word “activation” can merely refer to the initiation of the

activating of a particular function, as opposed to referring to both the initiation of the activating of the particular function and the subsequent duration in which the particular function is active. In these contexts, the phrase or a phrase similar to “activation initiation” may be used.

The term “program” in this disclosure should be interpreted as a set of instructions or modules that can be executed by one or more components in a system, such as a controller system or data processing device system, in order to cause the system to perform one or more operations. The set of instructions or modules can be stored by any kind of memory device, such as those described subsequently with respect to the memory device system **130** shown in FIG. 1. In addition, instructions or modules of a program may be described as being configured to cause the performance of a function or action.

The phrase “configured to” in this context is intended to include, for example, at least (a) instructions or modules that are presently in a form executable by one or more data processing devices to cause performance of the function (e.g., in the case where the instructions or modules are in a compiled and unencrypted form ready for execution), and (b) instructions or modules that are presently in a form not executable by the one or more data processing devices, but could be translated into the form executable by the one or more data processing devices to cause performance of the function (e.g., in the case where the instructions or modules are encrypted in a non-executable manner, but through performance of a decryption process, would be translated into a form ready for execution). The word “module” can be defined as a set of instructions.

The word “device” and the phrase “device system” both are intended to include, for example, one or more physical devices or sub-devices (e.g., pieces of equipment) that interact to perform one or more functions, regardless of whether such devices or sub-devices are located within a same housing or different housings. In this regard, the word “device” may equivalently be referred to as a “device system”.

Further, the phrase “in response to” may be used in this disclosure. For example, this phrase might be used in the following context, where an event A occurs in response to the occurrence of an event B. In this regard, such phrase includes, for example, that at least the occurrence of the event B causes or triggers the event A.

The phrase “physically coupled” is intended to include, for example, a coupling between two objects that involves a physical contacting of the two objects. The phrase “fixedly coupled” is intended to include, for example, a secure coupling between two objects that may, in some instances, not involve a mechanism configured to release the coupling of the two objects. The phrase “operatively coupled” is intended to include, for example, a coupling between two objects that transmits force, energy, information, or other influence at least from one of the two objects to the other of the two objects. An operative coupling does not exclude the possibility of a physical or fixed coupling in addition to the operative coupling.

FIG. 1 schematically illustrates a system **100**, according to some embodiments. The system **100** includes a data processing device system **110**, an input-output device system **120**, and a processor-accessible memory device system **130**. The processor-accessible memory device system **130** and the input-output device system **120** are communicatively connected to the data processing device system **110**.

The data processing device system **110** includes one or more data processing devices that implement methods by

35

controlling, driving, or otherwise interacting with various structural components described herein, including, but not limited to, one or more of the various structural components illustrated in FIGS. 2-5, 7, 8, and 10. Each of the phrases “data processing device”, “data processor”, “processor”, and “computer” is intended to include any data processing device, such as a central processing unit (“CPU”), a desktop computer, a laptop computer, a mainframe computer, a tablet computer, a personal digital assistant, a cellular phone, and any other device for processing data, managing data, or handling data, whether implemented with electrical, magnetic, optical, biological components, or otherwise.

The memory device system 130 includes one or more processor-accessible memory devices configured to store information, including the information needed to execute the methods, including, in some embodiments, some or all of one or more of the methods of FIG. 9, implemented by the data processing device system 110. The memory device system 130 may be a distributed processor-accessible memory device system including multiple processor-accessible memory devices communicatively connected to the data processing device system 110 via a plurality of computers and/or devices. On the other hand, the memory device system 130 need not be a distributed processor-accessible memory system and, consequently, may include one or more processor-accessible memory devices located within a single housing or data processing device.

Each of the phrases “processor-accessible memory” and “processor-accessible memory device” is intended to include any processor-accessible data storage device, whether volatile or nonvolatile, electronic, magnetic, optical, or otherwise, including but not limited to, registers, floppy disks, hard disks, Compact Discs, DVDs, flash memories, ROMs, and RAMs. In some embodiments, each of the phrases “processor-accessible memory” and “processor-accessible memory device” is intended to include or be a processor-accessible (or computer-readable) data storage medium. In some embodiments, each of the phrases “processor-accessible memory” and “processor-accessible memory device” is intended to include or be a non-transitory processor-accessible (or computer-readable) data storage medium. In some embodiments, the memory device system 130 may be considered to include or be a non-transitory processor-accessible (or computer-readable) data storage medium system. And, in some embodiments, the memory device system 130 may be considered to include or be a non-transitory processor-accessible (or computer-readable) data storage medium system.

The phrase “communicatively connected” is intended to include any type of connection, whether wired or wireless, between devices, data processors, or programs in which data may be communicated. Further, the phrase “communicatively connected” is intended to include a connection between devices or programs within a single data processor, a connection between devices or programs located in different data processors, and a connection between devices not located in data processors at all. In this regard, although the memory device system 130 is shown separately from the data processing device system 110 and the input-output device system 120, one skilled in the art will appreciate that the memory device system 130 may be located completely or partially within the data processing device system 110 or the input-output device system 120. Further in this regard, although the input-output device system 120 is shown separately from the data processing device system 110 and the memory device system 130, one skilled in the art will appreciate that such system may be located completely or

36

partially within the data processing system 110 or the memory device system 130, depending upon the contents of the input-output device system 120. Further still, the data processing device system 110, the input-output device system 120, and the memory device system 130 may be located entirely within the same device or housing or may be separately located, but communicatively connected, among different devices or housings. In the case where the data processing device system 110, the input-output device system 120, and the memory device system 130 are located within the same device, the system 100 of FIG. 1 can be implemented by a single application-specific integrated circuit (ASIC) in some embodiments.

The input-output device system 120 may include a mouse, a keyboard, a touch screen, a computer, a processor-accessible memory device, some or all of a catheter device system (e.g., FIGS. 3A, 3B, 4, or catheter system 500, described below), or any device or combination of devices from which a desired selection, desired information, instructions, or any other data is input to the data processing device system 110. The input-output device system 120 may include a user-activatable control system that is responsive to a user action. The input-output device system 120 may include any suitable interface for receiving a selection, information, instructions, or any other data from other devices or systems described in various ones of the embodiments. In this regard, the input-output device system 120 may include various ones or portions of other systems or devices described in various embodiments.

The input-output device system 120 also may include an image generating device system, a display device system, a processor-accessible memory device, some or all of a catheter device system (e.g., FIGS. 3A, 3B, 4, or catheter system 500, described below), or any device or combination of devices to which information, instructions, or any other data is output by the data processing device system 110. In this regard, if the input-output device system 120 includes a processor-accessible memory device, such memory device may or may not form part or all of the memory device system 130. The input-output device system 120 may include any suitable interface for outputting information, instructions, or any other data to other devices or systems described in various ones of the embodiments. In this regard, the input-output device system 120 may include various other devices or systems described in various embodiments.

Various embodiments of catheter systems are described herein. It should be noted that any catheter system described herein may also be referred to as a medical system. Some of the described devices of such systems are medical devices that are percutaneously or intravascularly deployed. Some of the described devices are deployed through a bodily opening that is accessible without puncturing, cutting or otherwise perforating bodily tissue to create an access to the bodily opening. Some of the described devices employ transducer-based devices or device systems. Some of the described devices are moveable between a delivery or unexpanded configuration in which a portion of the device is sized, shaped, or both for passage through a bodily opening leading to a bodily cavity, and an expanded or deployed configuration in which the portion of the device has a size, shape, or both too large for passage through the bodily opening leading to the bodily cavity. An example of an expanded or deployed configuration is when the portion of the catheter system is in its intended-deployed-operational state inside the bodily cavity. Another example of the expanded or deployed configuration is when the portion of the catheter system is being changed from the delivery configuration to

the intended-deployed-operational state to a point where the portion of the device now has a size, shape, or both too large for passage through the bodily opening leading to the bodily cavity.

In some example embodiments, the catheter system includes transducers that sense characteristics (e.g., convective cooling, permittivity, force) that distinguish between fluid, such as a fluidic tissue (e.g., blood), and tissue forming an interior surface of the bodily cavity. Such sensed characteristics can allow a medical device system to map the cavity, for example using positions of openings or ports into and out of the cavity to determine a position or orientation (i.e., pose), or both of the portion of the device in the bodily cavity. In some example embodiments, the described devices are capable of ablating tissue in a desired pattern within the bodily cavity. In some example embodiments, the devices are capable of sensing characteristics (e.g., electrophysiological activity) indicative of whether an ablation has been successful. In some example embodiments, the devices are capable of providing stimulation (e.g., electrical stimulation) to tissue within the bodily cavity. Electrical stimulation may include pacing.

FIG. 2 shows a portion of a catheter system, according to some embodiments, such portion including a transducer-based device 200, which may be at least part of a medical device useful in investigating or treating a bodily organ, for example a heart 202, according to some example embodiments. The transducer-based device 200 may also be referred to as a manipulable portion, due to its ability to have its size, shape, or both size and shape altered, according to some embodiments described below. Transducer-based device 200 can be percutaneously or intravascularly inserted into a portion of the heart 202, such as an intra-cardiac cavity like left atrium 204.

In the example of FIG. 2, the illustrated portion of the catheter system also includes a catheter 206, which may be inserted via the inferior vena cava 208 and may penetrate through a bodily opening in transatrial septum 210 from right atrium 212. In other embodiments, other paths may be taken.

Catheter 206 includes an elongated flexible rod or shaft member appropriately sized to be delivered percutaneously or intravascularly. Various portions of catheter 206 may be steerable. Catheter 206 may include one or more lumens. The lumen(s) may carry one or more communications or power paths, or both. For example, the lumens(s) may carry one or more electrical conductors 216 (two shown in this embodiment). Electrical conductors 216 provide electrical connections to transducer-based device 200 that are accessible externally from a patient in which the transducer-based device 200 is inserted.

In various embodiments, transducer-based device, or manipulable portion, 200 includes a frame or structure 218, which assumes an unexpanded configuration for delivery to left atrium 204. Structure 218 is expanded (i.e., shown in a deployed or expanded configuration in FIG. 2) upon delivery to left atrium 204 to position a plurality of transducers 220 (three called out in FIG. 2) proximate the interior surface formed by tissue 222 of left atrium 204. In this regard, it can be stated that one or more of the transducers 220 are moveable with one or more parts of the transducer-based device, or manipulable portion, 200. In some embodiments, at least some of the transducers 220 are used to sense a physical characteristic of a fluid (i.e., blood) or tissue 222, or both, that may be used to determine a position or orientation (i.e., pose), or both, of a portion of transducer-based device 200 within, or with respect to left atrium 204.

For example, transducers 220 may be used to determine a location of pulmonary vein ostia (not shown) or a mitral valve 226, or both. In some embodiments, at least some of the transducers 220 may be used to selectively ablate portions of the tissue 222. For example, some of the transducers 220 may be used to ablate a pattern or path around various ones of the bodily openings, ports or pulmonary vein ostia, for instance to reduce or eliminate the occurrence of atrial fibrillation.

FIGS. 3A and 3B show a catheter system (i.e., a portion thereof shown schematically) that includes a transducer-based device 300 according to one illustrated embodiment. The transducer-based device 300 may correspond to the transducer-based device 200 and, in this regard, may also be referred to as a manipulable portion, due to its ability to have its size, shape, or both size and shape altered, according to some embodiments described below. Transducer-based device 300 may include a plurality of elongate members 304 (three called out in each of FIGS. 3A and 3B) and a plurality of transducers 306 (three called out in FIG. 3A, and three called out in FIG. 3B as 306a, 306b and 306c). As will become apparent, the plurality of transducers 306 are positionable within a bodily cavity. For example, in some embodiments, the transducers 306 are able to be positioned in a bodily cavity by movement into, within, or into and within the bodily cavity, with or without a change in a particular configuration of the plurality of transducers 306. In some embodiments, the plurality of transducers 306 are arrangeable to form a two- or three-dimensional distribution, grid or array of the transducers capable of mapping, ablating, or stimulating an inside surface of a bodily cavity or lumen without requiring mechanical scanning. As shown, for example, in FIG. 3A, the plurality of transducers 306 are arranged in a distribution receivable in a bodily cavity, as the transducer-based device 300 and its plurality of transducers 306 are located within the catheter sheath 312. Stated differently, in FIG. 3A, for example, the plurality of transducers 306 are arranged in a distribution suitable for delivery to a bodily cavity. (It should also be noted, however, that the expanded or deployed configuration (e.g., FIGS. 2, 3B) may also be considered to have the transducers 306 arranged in a distribution receivable in a bodily cavity, as the transducer-based device 300 and its transducers 306 may be returned to the delivery configuration of FIG. 3A, for example.) In some embodiments, each of the transducers 306 includes an electrode 315 (one called out in FIG. 3B) having an energy transmission surface 319 (one called out in FIG. 3B) suitable for transmitting energy in various directions. In some embodiments, tissue-ablating energy is transmitted toward or away from an electrode 315. In some embodiments, tissue-based electrophysiological energy is transmitted toward an electrode 315.

The elongate members 304 form part of a manipulable portion, and in various embodiments, are arranged in a frame or structure 308 that is selectively moveable between an unexpanded or delivery configuration (i.e., as shown in FIG. 3A) and an expanded or deployed configuration (i.e., as shown in FIG. 3B) that may be used to position elongate members 304 against a tissue surface within the bodily cavity or position the elongate members 304 in the vicinity of or in contact with the tissue surface. In this regard, it may also be stated that the transducer-based device, or manipulable portion, 300 is selectively moveable between an unexpanded or delivery configuration (i.e., as shown in FIG. 3A) and an expanded or deployed configuration (i.e., as shown in FIG. 3B). In some embodiments, the transducer-based device, or manipulable portion, 300, (e.g., the structure 308

thereof) has a size, shape, or both a size and a shape in the unexpanded or delivery configuration suitable for percutaneous delivery through a bodily opening (for example, via catheter sheath 312, not shown in FIG. 3B) to the bodily cavity. In some embodiments, structure 308 has a size, shape, or both a size and a shape in the expanded or deployed configuration too large for percutaneous delivery through a bodily opening (i.e., via catheter sheath 312) to the bodily cavity. The elongate members 304 may form part of a flexible circuit structure (i.e., also known as a flexible printed circuit board (PCB) circuit). The elongate members 304 can include a plurality of different material layers, and each of the elongate members 304 can include a plurality of different material layers. The structure 308 can include a shape memory material, for instance Nitinol. The structure 308 can include a metallic material, for instance stainless steel, or non-metallic material, for instance polyimide, or both a metallic and non-metallic material by way of non-limiting example. The incorporation of a specific material into structure 308 may be motivated by various factors including the specific requirements of each of the unexpanded or delivery configuration and expanded or deployed configuration, the required position or orientation (i.e., pose) or both of structure 308 in the bodily cavity, or the requirements for successful ablation of a desired pattern. The number of elongate members depicted in FIG. 3B is non-limiting.

FIG. 4 is a schematic side elevation view of at least a portion of a transducer-based device 400 that includes a flexible circuit structure 401 that is employed to provide a plurality of transducers 406 (two called out) according to an example embodiment. In some embodiments, the flexible circuit structure 401 may form part of a structure (e.g., structure 308) that is selectively moveable between a delivery configuration sized for percutaneous delivery and an expanded or deployed configuration sized too large for percutaneous delivery. In some embodiments, the flexible circuit structure 401 may be located on, or form at least part of, of a structural component (e.g., elongate member 304) of a transducer-based device system.

The flexible circuit structure 401 can be formed by various techniques including flexible printed circuit techniques. In some embodiments, the flexible circuit structure 401 includes various layers including flexible layers 403a, 403b and 403c (i.e., collectively flexible layers 403). In some embodiments, each of flexible layers 403 includes an electrical insulator material (e.g., polyimide). One or more of the flexible layers 403 can include a different material than another of the flexible layers 403. In some embodiments, the flexible circuit structure 401 includes various electrically conductive layers 404a, 404b and 404c (collectively electrically conductive layers 404) that are interleaved with the flexible layers 403. In some embodiments, each of the electrically conductive layers 404 is patterned to form various electrically conductive elements. For example, electrically conductive layer 404a is patterned to form a respective electrode 415 of each of the transducers 406. Electrodes 415 have respective electrode edges 415-1 that form a periphery of an electrically conductive surface associated with the respective electrode 415. FIG. 3B shows another example of electrode edges 315-1 and illustrates that the electrode edges can define electrically-conductive-surface-peripheries of various shapes.

Returning to FIG. 4, electrically conductive layer 404b is patterned, in some embodiments, to form respective temperature sensors 408 for each of the transducers 406 as well as various leads 410a arranged to provide electrical energy

to the temperature sensors 408. In some embodiments, each temperature sensor 408 includes a patterned resistive member 409 (two called out) having a predetermined electrical resistance. In some embodiments, each resistive member 409 includes a metal having relatively high electrical conductivity characteristics (e.g., copper). In some embodiments, electrically conductive layer 404c is patterned to provide portions of various leads 410b arranged to provide an electrical communication path to electrodes 415. In some embodiments, leads 410b are arranged to pass through vias in flexible layers 403a and 403b to connect with electrodes 415. Although FIG. 4 shows flexible layer 403c as being a bottom-most layer, some embodiments may include one or more additional layers underneath flexible layer 403c, such as one or more structural layers, such as a steel or composite layer. These one or more structural layers, in some embodiments, are part of the flexible circuit structure 401 and can be part of, e.g., elongate member 304. In addition, although FIG. 4 shows only three flexible layers 403a-403c and only three electrically conductive layers 404a-404c, it should be noted that other numbers of flexible layers, other numbers of electrically conductive layers, or both, can be included.

In some embodiments, electrodes 415 are employed to selectively deliver RF energy to various tissue structures within a bodily cavity (e.g., an intra-cardiac cavity). The energy delivered to the tissue structures may be sufficient for ablating portions of the tissue structures. The energy delivered to the tissue may be delivered to cause monopolar tissue ablation, bipolar tissue ablation or blended monopolar-bipolar tissue ablation by way of non-limiting example.

Energy that is sufficient for tissue ablation may be dependent upon factors including tissue characteristics, transducer location, size, shape, relationship with respect to another transducer or a bodily cavity, material or lack thereof between transducers, et cetera.

In some embodiments, each electrode 415 is employed to sense an electrical potential in the tissue proximate the electrode 415. In some embodiments, each electrode 415 is employed in the generation of an intra-cardiac electrogram. In some embodiments, each resistive member 409 is positioned adjacent a respective one of the electrodes 415. In some embodiments, each of the resistive members 409 is positioned in a stacked or layered array with a respective one of the electrodes 415 to form at least part of a respective one of the transducers 406. In some embodiments, the resistive members 409 are connected in series to allow electrical current to pass through all of the resistive members 409. In some embodiments, leads 410a are arranged to allow for a sampling of electrical voltage in between each resistive member 409. This arrangement allows for the electrical resistance of each resistive member 409 to be accurately measured. The ability to accurately measure the electrical resistance of each resistive member 409 may be motivated by various reasons including determining temperature values at locations at least proximate the resistive member 409 based at least on changes in the resistance caused by convective cooling effects (e.g., as provided by blood flow). In some embodiments in which the transducer-based device is deployed in a bodily cavity (e.g., when the transducer-based device 300 is part of a catheter system and may be arranged to be percutaneously or intravascularly delivered to a bodily cavity via a catheter), it may be desirable to perform various mapping procedures in the bodily cavity. For example, when the bodily cavity is an intra-cardiac cavity, a desired mapping procedure can include mapping electrophysiological activity in the intra-cardiac cavity. Other desired mapping procedures can include mapping of various

41

anatomical features within a bodily cavity. An example of the mapping performed by devices according to various embodiments may include locating the position of the ports of various bodily openings positioned in fluid communication with a bodily cavity. For example, in some embodiments, it may be desired to determine the locations of various ones of the pulmonary veins or the mitral valve that each interrupts an interior surface of an intra-cardiac cavity such as a left atrium.

Referring to FIGS. 3A, 3B, transducer-based device or manipulable portion 300 may communicate with, receive power from, or be controlled by a control system 322. In some embodiments, elongate members 304 can form a portion of an elongated cable 316 of control leads 317, for example by stacking multiple layers, and terminating at a connector 321 or other interface with control system 322. The control leads 317 may correspond to the electrical connectors 216 in FIG. 2 in some embodiments. The control system 322 may include a controller 324 that may include a data processing device system 310 (e.g., data processing device system 110 from FIG. 1) and a memory device system 330 (e.g., memory device system 130 from FIG. 1) that stores data and instructions that are executable by the data processing device system 310 to process information received from transducer-based device 300 or to control operation of transducer-based device 300, for example activating various selected transducers 306 to ablate tissue. Controller 324 may include one or more controllers.

In some embodiments, the controller 324 may be configured to control deployment, expansion, retraction, or other manipulations of the shape, positioning, or both shape and positioning of the transducer-based device (e.g., manipulable portion) 300 at least by driving (e.g., by an electric or other motor) movement of various actuators or other catheter system components described below, with respect to, e.g., FIGS. 5 and 7.

In this regard, in some embodiments, some of which are described later in this disclosure, the controller 324 is at least part of a control system, which may include one or more actuators, configured to advance at least part of the transducer-based device (e.g., 200, 300, 400, or 502), at least a portion of which may be considered a manipulable portion, out of the catheter sheath 312, retract at least part of the transducer-based device back into the catheter sheath 312, expand, contract, or otherwise change at least part of the shape of the transducer-based device.

Control system 322 may include an input-output device system 320 (e.g., an example of 120 from FIG. 1) communicatively connected to the data processing device system 310 (i.e., via controller 324 in some embodiments). Input-output device system 320 may include a user-activatable control that is responsive to a user action. Input-output device system 320 may include one or more user interfaces or input/output (I/O) devices, for example one or more display device systems 332, speaker device systems 334, keyboards, mice, joysticks, track pads, touch screens or other transducers to transfer information to, from, or both to and from a user, for example a care provider such as a health care provider or technician. For example, output from a mapping process may be displayed on a display device system 332.

Control system 322 may also include an energy source device system 340 including one or more energy source devices connected to transducers 306. In this regard, although FIG. 3A shows a communicative connection between the energy source device system 340 and the controller 324 (and its data processing device system 310),

42

the energy source device system 340 may also be connected to the transducers 306 via a communicative connection that is independent of the communicative connection with the controller 324 (and its data processing device system 310). For example, the energy source device system 340 may receive control signals via the communicative connection with the controller 324 (and its data processing device system 310), and, in response to such control signals, deliver energy to, receive energy from, or both deliver energy to and receive energy from one or more of the transducers 306 via a communicative connection with such transducers 306 (e.g., via one or more communication lines through catheter body 314, elongated cable 316 or catheter sheath 312) that does not pass through the controller 324. In this regard, the energy source device system 340 may provide results of its delivering energy to, receiving energy from, or both delivering energy to and receiving energy from one or more of the transducers 306 to the controller 324 (and its data processing device system 310) via the communicative connection between the energy source device system 340 and the controller 324.

In any event, the number of energy source devices in the energy source device system 340 may be fewer than the number of transducers in some embodiments. The energy source device system 340 may, for example, be connected to various selected transducers 306 to selectively provide energy in the form of electrical current or power (e.g., RF energy), light or low temperature fluid to the various selected transducers 306 to cause ablation of tissue. The energy source device system 340 may, for example, selectively provide energy in the form of electrical current to various selected transducers 306 and measure a temperature characteristic, an electrical characteristic, or both at a respective location at least proximate each of the various transducers 306. The energy source device system 340 may include as its energy source devices various electrical current sources or electrical power sources. In some embodiments, an indifferent electrode 326 is provided to receive at least a portion of the energy transmitted by at least some of the transducers 306. Consequently, although not shown in FIG. 3A, the indifferent electrode 326 may be communicatively connected to the energy source device system 340 via one or more communication lines in some embodiments. In addition, although shown separately in FIG. 3A, indifferent electrode 326 may be considered part of the energy source device system 340 in some embodiments. In some embodiments, the indifferent electrode 326 is provided outside the body or at least the bodily cavity in which the transducer-based device (e.g., 200, 300, or 400) or catheter system 500 is, at least in part, located.

In some embodiments, the energy source device system 340 may include one or more driving motors configured to drive movement, in response to instructions from the controller 324, of various actuators or other catheter system components described, below, with respect to, e.g., FIGS. 5 and 7 to control deployment, expansion, retraction, or other manipulations of the shape, positioning, or both shape and positioning of the transducer-based device (e.g., manipulable portion) 300.

It is understood that input-output device system 320 may include other systems. In some embodiments, input-output device system 320 may optionally include energy source device system 340, transducer-based device 300 or both energy source device system 340 and transducer-based device 300 by way of non-limiting example.

Structure 308 of transducer-based device 300 can be delivered and retrieved through a catheter member, for

example, a catheter sheath 312. In some embodiments, the structure 308 provides expansion and contraction capabilities for a portion of a medical device (e.g., an arrangement, distribution or array of transducers 306). The transducers 306 can form part of, be positioned or located on, mounted or otherwise carried on the structure and the structure may be configurable to be appropriately sized to slide within a lumen of catheter sheath 312 in order to be deployed percutaneously or intravascularly. FIG. 3A shows one embodiment of such a structure. In some embodiments, each of the elongate members 304 includes a respective distal end 305 (only one called out), a respective proximal end 307 (only one called out) and an intermediate portion 309 (only one called out) positioned between the proximal end 307 and the distal end 305. The respective intermediate portion 309 of each elongate member 304 includes a first or front surface 318a that is positionable to face an interior tissue surface within a bodily cavity and a second or back surface 318b opposite across a thickness of the intermediate portion 309 from the front surface 318a. In various embodiments, the intermediate portion 309 of each of the elongate members 304 includes a respective pair of side edges of the front surface 318a, the back surface 318b, or both the front surface 318a and the back surface 318b, the side edges of each pair of side edges opposite to one another, the side edges of each pair of side edges extending between the proximal end 307 and the distal end 305 of the respective elongate member 304. In some embodiments, each pair of side edges includes a first side edge 327a (only one called out in FIG. 3A) and a second side edge 327b (only one called out in FIG. 3A). In some embodiments, each of the elongate members 304, including each respective intermediate portion 309, is arranged front surface 318a-toward-back surface 318b in a stacked array during an unexpanded or delivery configuration (e.g., FIG. 3A, 5G). In many cases, a stacked array allows the structure 308 to have a suitable size for percutaneous or intravascular delivery. A stacked array can allow structure 308 to have a spatially efficient size for delivery through a lumen of catheter sheath 312. In some embodiments, the elongate members 304 are arranged to be introduced into a bodily cavity distal end 305 first. For clarity, not all of the elongate members 304 of structure 308 are shown in FIG. 3A. A flexible catheter body or shaft 314 is used to deliver structure 308 through catheter sheath 312. In some embodiments, each elongate member includes a twisted portion proximate proximal end 307 (e.g., also FIG. 5B, discussed below).

In some embodiments, each of the elongate members 304 is arranged in a fanned arrangement 370 in FIG. 3B. In some embodiments, the fanned arrangement 370 is formed during the expanded or deployed configuration in which the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof is manipulated to have a size, shape, or both size and shape too large for percutaneous or intravascular delivery, for example a size, shape, or both size and shape too large for percutaneous or intravascular delivery toward a bodily cavity, or a size, shape, or both size and shape too large for percutaneous or intravascular delivery away from a bodily cavity. In some embodiments, the fanned arrangement 370 is formed during the expanded or deployed configuration in which the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof is manipulated to have a size, shape, or both size and shape too large for delivery through a lumen of catheter sheath 312, for example, a size, shape, or both size and shape too large for delivery through a lumen of catheter sheath 312 toward a

bodily cavity, or a size, shape, or both size and shape too large for delivery through a lumen of catheter sheath 312 away from a bodily cavity.

In some embodiments, the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof includes a proximal portion 308a having a first domed shape 309a and a distal portion 308b having a second domed shape 309b when the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof is in the expanded or deployed configuration. In some embodiments, the proximal and the distal portions 308a, 308b include respective portions of elongate members 304. In some embodiments, the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof is arranged to be delivered or advanced distal portion 308b first into a bodily cavity when the transducer-based device (e.g., manipulable portion) 300 or structure 308 thereof is in the unexpanded or delivery configuration as shown in FIG. 3A. In some embodiments, the proximal and the distal portions 308a, 308b are arranged in a clam shell configuration in the expanded or deployed configuration shown in FIG. 3B. In various example embodiments, each of the front surfaces 318a (two called out in FIG. 3B) of the intermediate portions 309 of the plurality of elongate members 304 face outwardly from the structure 308 when the structure 308 is in the deployed configuration. In various example embodiments, each of the front surfaces 318a of the intermediate portions 309 of the plurality of elongate members 304 are positioned adjacent an interior tissue surface of a bodily cavity in which the structure 308 (i.e., in the deployed configuration) is located. In various example embodiments, each of the back surfaces 318b (two called out in FIG. 3B) of the intermediate portions 309 of the plurality of elongate members 304 face an inward direction when the structure 308 is in the deployed configuration.

The transducers 306 can be arranged in various distributions or arrangements in various embodiments. In some embodiments, various ones of the transducers 306 are spaced apart from one another in a spaced apart distribution in the delivery configuration shown in FIG. 3A. In some embodiments, various ones of the transducers 306 are arranged in a spaced apart distribution in the deployed configuration shown in FIG. 3B. In some embodiments, various pairs of transducers 306 are spaced apart with respect to one another. In some embodiments, various regions of space are located between various pairs of the transducers 306. For example, in FIG. 3B the transducer-based device 300 includes at least a first transducer 306a, a second transducer 306b and a third transducer 306c (all collectively referred to as transducers 306). In some embodiments each of the first, the second, and the third transducers 306a, 306b and 306c are adjacent transducers in the spaced apart distribution. In some embodiments, the first and the second transducers 306a, 306b are located on different elongate members 304 while the second and the third transducers 306b, 306c are located on a same elongate member 304. In some embodiments, a first region of space 350 is between the first and the second transducers 306a, 306b. In some embodiments, the first region of space 350 is not associated with any physical portion of structure 308. In some embodiments, a second region of space 360 associated with a physical portion of device 300 (i.e., a portion of an elongate member 304) is between the second and the third transducers 306b, 306c. In some embodiments, each of the first and the second regions of space 350, 360 does not include a transducer of transducer-based device 300. In some embodiments, each of the first and the second regions

of space **350**, **360** does not include any transducer. It is noted that other embodiments need not employ a group of elongate members **304** as employed in the illustrated embodiment. For example, other embodiments may employ a structure having one or more surfaces, at least a portion of the one or more surfaces defining one or more openings in the structure. In these embodiments, a region of space not associated with any physical portion of the structure may extend over at least part of an opening of the one or more openings. In other example embodiments, other structures may be employed to support or carry transducers of a transducer-based device such as a transducer-based catheter device. For example, an elongated catheter member may be used to distribute the transducers in a linear or curvilinear array. Basket catheters or balloon catheters may be used to distribute the transducers in a two-dimensional or three-dimensional array.

In some embodiments, a manipulable portion, such as, but not limited to, a transducer-based device (e.g., **200** or **300**) is manipulated to transition between a delivery configuration (e.g., FIG. **3A**) and an expanded or deployed configuration (e.g., FIG. **3B**) manually (e.g., by a user's manual operation) or at least in part by way of motor-based driving (e.g., from the energy source device system **340**) of one or more actuators or other catheter system components described, below, with respect to, e.g., FIGS. **5** and **7**. Motor-based driving may augment or otherwise be in response to manual actions, may be responsive to automated control of a data processing device system (e.g., **110** in FIG. **1** or **310** in FIGS. **3A** and **3B**), or may use a hybrid manual-automated approach.

In this regard, each of the individual figures of FIG. **5** and FIG. **7** shows some or all of a catheter system **500**, which includes a manipulable portion **502**, according to various embodiments. In this regard, it should be noted that any of the catheter systems described herein may also be referred to as a medical system and, consequently, that catheter system **500** may be referred to as a medical system **500**. In some embodiments, the manipulable portion **502** corresponds to the transducer-based device **200** or **300**, although the manipulable portion **502** need not be a transducer-based device and may be some other form of catheter-based manipulable portion (e.g., a stent or other implant).

According to some embodiments, the catheter system **500** includes several different types of motions to control the deployment, retraction, positioning, size, and shape of the manipulable portion **502**. These different types of motions may include coiling, uncoiling, fanning, un-fanning, bifurcated doming, flattening, clam shelling, or a combination of some or all of these motions. In some embodiments, these motions facilitate accommodation of different bodily cavity sizes (e.g., different atrium sizes), as well as proper positioning of the manipulable-portion within the bodily cavity (e.g., atrium) and contact with one or more tissue walls of the bodily cavity.

With respect to these types of motions, for example, deployment of the manipulable portion **502** may involve a coiling of the manipulable portion **502** by way of a built-in predisposition of the manipulable portion **502** to autonomously coil when released from the confines of a catheter sheath **512** or some other confining member, by way of a control element **513** (e.g., a cable **513b**), or by way of both autonomous coiling and a control element. See, e.g., the sequence of FIGS. **5H**, **5I**, and **5J**, discussed in detail below. In some embodiments, the control element (e.g., cable **513b**) is physically coupled to the manipulable portion **502** (e.g., at least proximate to a distal end **505a** thereof) to transmit force

to the manipulable portion and to control a positioning of at least part of the manipulable portion **502** during coiling. Uncoiling of the manipulable portion **502** during retraction is described in more detail below, with respect to at least the sequence of Figures of **5J**, **5I**, and **5H**. Such uncoiling may occur by way of a control element **513** (e.g., a cable **513b**), by way of a containment force applied by the catheter sheath **512** or some other confining member as the manipulable portion **502** is retracted into the catheter sheath **512** or other confining member, or by way of both a control element and a containment force of a confining member into which the manipulable portion **502** is retracted.

In some embodiments, the coiling/uncoiling motion during deployment/retraction of the manipulable portion **502** is caused and controlled, at least in part, by activation or movement of a second particular actuator **540b** and an internal receiving mechanism **546** with respect to a first particular actuator **540a**, which may act as an anchor in some configurations. In some embodiments, the coiling/uncoiling motion during deployment/retraction involves a metering of a portion of the control element **513** (e.g., a cable **513b**) with different rates under the control of a master slider **556a**, a sleeve slider **556b**, and the second particular actuator **540b**, which are described in more detail, below, with respect to at least FIGS. **7A** and **7B**.

In some embodiments, once the manipulable portion **502** is extended outside of the distal end **512b** of the catheter sheath **512**, as shown, for example, at least in FIGS. **5L-1** and **5L-2**, the manipulable portion **502** may be fanned, or additionally fanned, as shown in FIGS. **5M-1** and **5M-2** by action of a sliding actuator **572**, of which a cover **520a** is a part, which are described in more detail, below, with respect to at least FIGS. **5S-1** and **5S-2**. Un-fanning of the manipulable portion **502** to return the manipulable portion **502** back into a retraction-ready shape may also be controlled by the sliding actuator **572**, as described in more detail, below.

In some embodiments, at least when the manipulable portion **502** is fanned, different portions **508a**, **508b** (e.g., hemispheres in some embodiments) of the manipulable portion **502** may be controlled to have different domed shapes. This type of motion may be referred to as bifurcated doming and is described in more detail, below, with respect to FIGS. **5M-1** and **5M-2**, for example. This type of motion may be controlled by positioning of cover **520a**, described in more detail, below, with respect to FIGS. **5S-1** and **5S-2**, for example. FIGS. **5N-5Q**, discussed below, also illustrate different domed shapes to which the manipulable portion **502** may be controlled to have, according to some embodiments.

In some embodiments, at least when the manipulable portion **502** is fanned, the manipulable portion **502** may be flattened, as described in more detail, below, with respect to FIGS. **5N** and **5O**. In some embodiments, this flattening motion may be caused and controlled by activation or action of the first particular actuator **540a**, which is described in more detail, below, with respect to FIGS. **5S**, **7A**, and **7B**.

In some embodiments, at least when the manipulable portion **502** is fanned, the manipulable portion **502** may be subjected to clam shelling as described in more detail, below, with respect to FIGS. **5P** and **5Q**. In some embodiments, this clam shelling may be caused and controlled by activation or action of the second particular actuator **540b**, which is described in more detail, below, with respect to FIGS. **5S**, **7A**, and **7B**.

Now, each of the figures of FIG. **5** (collectively referred to as "FIG. **5**") will be described. FIG. **5** illustrate various views of various aspects of medical systems or catheter

systems, according to various embodiments. In this regard, the systems of FIG. 5 (as well as the other remaining figures) may be particular implementations of the systems of FIGS. 2 and 3, according to some embodiments. Accordingly, descriptions herein regarding the systems of FIGS. 2 and 3 apply to the systems of FIG. 5 (as well as the other remaining figures), according to some embodiments.

As shown in FIG. 5A, catheter system 500 includes various devices including a catheter shaft member 500a (also referred to as shaft member 500a) and, in some embodiments, a catheter sheath member 500b (also referred to as sheath member 500b). Shaft member 500a includes a shaft 510 (e.g., the same or similar to catheter body 314) that includes a proximal end 510a, a distal end 510b, and an intermediate or elongated portion 510c extending between the proximal end 510a and the distal end 510b (e.g., extending along a path that connects proximal end 510a and distal end 510b). In some embodiments associated with various ones of FIG. 5, the manipulable portion 502 is located at least proximate the distal end 510b.

Catheter sheath member 500b includes a catheter sheath 512 (e.g., the same or similar to sheath 312) that includes proximal end 512a, a distal end 512b and a body portion 512c between the proximal end 512a and the distal end 512b. In various embodiments, catheter sheath 512 includes one or more lumens, each of at least some of the one or more lumens extending between proximal end 512a and distal end 512b (e.g., extending along a path that connects proximal end 512a and distal end 512b). In various embodiments associated with various ones of FIG. 5, catheter sheath 512 includes a first lumen 512d extending between (or connecting, in some embodiments) proximal end 512a and distal end 512b. Catheter sheath member 500b is provided in various embodiments to provide a passageway for at least a portion of shaft member 500a (e.g., a part of shaft 510) to be delivered therethrough to a location within a body during a medical procedure. In some embodiments, catheter sheath member 500b is deployed percutaneously or intravascularly into a body. In this regard, it may be stated that at least part of the shaft 510 is sized for percutaneous delivery to the bodily cavity. In various embodiments, at least a portion of catheter sheath member 500b (e.g., at least a portion of the catheter sheath 512) is delivered distal end 512b first through a naturally occurring bodily opening toward a bodily cavity. For instance, the catheter sheath 512 may be receivable in, insertable into, or positionable in a bodily opening. In some of these various embodiments, the bodily opening is accessed by a natural orifice or port provided by the body. In some of these embodiments, the bodily opening is accessed by a perforation made in bodily tissue. In various embodiments, a portion or part of shaft member 500a (e.g., at least part of the shaft 510) is received in, receivable in, or sized for delivery through the first lumen 512d of the catheter sheath 512 to a bodily cavity or to deliver the manipulable portion 502 through the first lumen 512d of the catheter sheath 512 to a bodily cavity (e.g., a bodily vessel, chamber or cavity within a bodily organ). In this regard, in some embodiments, at least the distal end 510b of the shaft 510 is sized for delivery through a bodily opening leading to a bodily cavity located in a body. It is understood that, although each of shaft 510 and catheter sheath 512 is depicted in FIG. 5A in an essentially straight configuration, each of shaft 510 (or at least part of the shaft 510 receivable in the lumen 512d of the catheter sheath 512) and catheter sheath 512 may be flexible or bendable or may include one or more flexible or bendable portions that allow bending or deflection or the assumption of a bent or curved (e.g.,

arcuate) form, e.g., during or for delivery to a bodily cavity. In various embodiments, shaft member 500a is arranged with respect to catheter sheath member 500b such that the distal end 510b of shaft 510 is configured, arranged, or sized to be delivered through the first lumen 512d of the catheter sheath 512 prior to at least the elongated portion 510c of the shaft 510, when the distal end 510b of shaft 510 is delivered toward or to the bodily cavity. In various embodiments, shaft member 500a is arranged with respect to catheter sheath member 500b such that the distal end 510b of shaft 510 is configured, arranged, or sized to be delivered through the first lumen 512d of the catheter sheath 512 in a direction extending from the proximal end 512a of catheter sheath 512 toward the distal end 512b of catheter sheath 512 when the distal end 510b of shaft 510 is delivered toward or to the bodily cavity.

In various embodiments, the manipulable portion 502 includes a proximal end 501a (e.g., in the vicinity of elongate member proximal ends 507 in FIG. 5G), a distal end 501b (e.g., in the vicinity of elongate member distal ends 505 in FIG. 5G), and an elongated part 501c (e.g., FIG. 5G) extending between the proximal end 501a and the distal end 501b of the manipulable portion 502. In some embodiments, the manipulable portion is delivered and advanced outwardly, e.g., distal end 501b first with respect to or as compared to other parts of the manipulable portion 502, through the first lumen 512d of the catheter sheath 512 toward or to the bodily cavity as the shaft 510 is advanced accordingly through first lumen 512d. It is noted that each of shaft 510 and catheter sheath 512 has a respective elongated portion that can have longitudinal or axial components. For example, the shaft 510 has a longitudinal length 510d extending between the respective proximal end 510a and distal end 510b, according to some embodiments. Similarly, the sheath 512 has a longitudinal length 512f extending between the respective proximal end 512a and distal end 512b, according to some embodiments. As used in this disclosure, words such as “longitudinal” or “axial” are not limited to various members having generally straight forms but can include members that have bent or arcuate forms or forms that have been bent from a generally straight form into a generally non-straight form.

In various embodiments, manipulable portion 502 is selectively configurable or moveable, e.g., based at least upon user (e.g., a health care provider, technician, or other user) input (e.g., by way of actuators 540a, 540b, or 546 described with respect to FIG. 7, below, by way of actuator 572 described with respect to FIG. 5S, below, or by relative movement of the shaft 510 and catheter sheath 512) or other sensory input (e.g., from sensors in the input-output device system 120 of FIG. 1), into various configurations. For example, in some embodiments, the manipulable portion 502 may form at least part of a steerable portion of shaft member 500a. Catheter devices employing steerable portions may be used to better negotiate tortuous paths sometimes encountered during delivery to a bodily cavity. Catheter devices employing steerable portions may be employed to better achieve a desired positioning of various devices (e.g., implants or transducer systems). In some embodiments, the manipulable portion 502 may be selectively detachable from the shaft member 500a. For example, the manipulable portion 502 may, in some embodiments, form part of an implant (e.g., a stent). In some of these embodiments, an implant provided at least in part by the manipulable portion 502 may be selectively configurable or moveable (e.g., by way of a modulation or other actuator described in this disclosure) between a delivery configura-

49

tion in which the implant is appropriately sized for delivery through the first lumen **512d** toward or to a particular location in the bodily opening or bodily cavity and a deployed configuration in which the implant is sized too large for delivery through the first lumen **512d** toward or to the particular location in the bodily opening or bodily cavity. In some of these embodiments, the implant may be positioned in the deployed configuration when implanted or otherwise brought into engagement with tissue (e.g., a stent that is selective expanded to grip or to otherwise be secured within a bodily vessel).

In some embodiments associated with various ones of FIG. 5, manipulable portion **502** forms a part of a transducer-based device (e.g., **200**, **300**) with various sets of one or more transducers located on, or forming part of the manipulable portion **502**. For example, in some embodiments, manipulable portion **502** includes a structure **502a** (e.g., the same or similar to structure or frame **308**) and various transducers **506** (not shown for clarity in FIG. 5A, but may be the same or similar to transducers **220**, **306**, **406**) that are located on or carried by a surface of the manipulable portion **502** or the structure **502a** thereof. In a manner that is the same or similar to other embodiments described above in this disclosure, manipulable portion **502** or structure **502a** is selectively configurable or moveable (e.g., by way of a modulation or other actuator described in this disclosure) between a delivery configuration in which at least the structure **502a** is appropriately sized, shaped, or both sized and shaped for delivery through the first lumen **512d** of the catheter sheath **512** at least toward or to a bodily cavity located in a body and an expanded or deployed configuration in which at least the structure **502a** is sized, shaped, or both sized and shaped too large for delivery through the first lumen **512d** of the catheter sheath **512** at least toward or to the bodily cavity. In various embodiments, the manipulable portion **502** or structure **502a** thereof is physically coupled to the shaft **510** at a location at least proximate the distal end **510b** of the shaft **510**. In this regard, the manipulable portion **502** or structure **502a** thereof may include a plurality of elongate members **504** (two called out in FIG. 5A) that are physically coupled to shaft **510**, which is employed to transport the elongate members **504** through first lumen **512d** when the structure **502a** is in a delivery configuration. The number of elongate members **504** shown in various ones of FIG. 5 is non-limiting. An enlarged view of the manipulable portion **502** illustrated in FIG. 5A is shown in FIG. 5C, which is described in more detail below.

FIG. 5B is an isometric view of a representative one of the elongate members **504** in an initial or predisposed configuration as employed in some embodiments. Various dimensions of the representative one of the elongate member **504** have been exaggerated for clarity in FIG. 5B. Each of the elongate members **504** includes a respective first or distal end **505** and a respective second or proximal end **507**. Each intermediate portion includes a respective length between the respective proximal and distal ends **507**, **505** of the elongate member **504**. Each elongate member **504** includes a respective length between the respective proximal and distal ends **507**, **505** of the elongate member **504**. In various embodiments, two or more of the elongate members **504** may have substantially equal lengths or substantially unequal lengths. In various example embodiments, a respective portion of each of the elongate members **504** has a length that is at least approximately equal to or greater than a circumference of a portion of an interior tissue surface of a bodily cavity into which the elongate member **504** is to be positioned at least proximate to when the manipulable

50

portion **502** is in an expanded or deployed configuration. The circumference of the portion of the interior tissue surface may have a measured or anticipated value. In a manner that is the same or similar to other described embodiments, a set of transducer elements **506** (two called out) are distributed along a surface (e.g., surface **518a**) of each of various ones of the elongate members **504**. In some example embodiments, each elongate member **504** includes at least a portion of a flexible circuit structure (e.g., the same or similar to that employed by embodiments of FIG. 4) that at least provides an electrically communicative path to various ones of the transducer elements **506**.

In various embodiments, each of the elongate members **504** includes a plurality of various portions including first portion **509a**, second portion **509b**, and third portion **509c** (collectively portions **509**) arranged between the respective proximal and distal ends **507**, **505** of the elongate member **504**. The second portion **509b**, which may be considered an intermediate portion of the respective elongate member **504**, may be positioned between the first (e.g., distal) end **505** and the second (e.g., proximal) end **507** of the respective elongate member **504**. In some embodiments, each intermediate portion **509b** includes a set of two opposing major faces or surfaces **518** denominated as a front surface **518a** and a back surface **518b** in FIG. 5B. The two opposing surfaces **518** may be separated from one another by a thickness **517** of the elongate member **504**, such that the back surface **518b** is opposite across the thickness **517** from the front surface **518a**. In some embodiments, each of one or more of portions **509** may be considered an intermediate portion of the respective elongate member **504**. In FIG. 5B, the third portion **509c**, positioned between the first and the second portions **509a**, **509b**, and first portion **509a** is located along the elongate member **504** relatively closer to proximal end **507** than to distal end **505**, and the second portion **509b** is located along the elongate member **504** relatively closer to distal end **505** than to proximal end **507**. In various embodiments, the various portions **509** are combined in a unitary structure. In various embodiments, a number of the respective portions **509** of various ones of the elongate members **504** include various distortions or deformations. As used in reference to this context, the words "distortion" or "deformation" are used interchangeably herein to mean modification in shape away from an elongated strip-like form that, prior to any distortion or deformation, was predominately a body with a relatively small thickness as compared to a length or width, although major faces of the body may not necessarily have smooth planar surfaces. For example, the respective second portion **509b** of the representative elongate member **504** shown in FIG. 5B has a coiled profile (e.g., a profile that curves or curls back on itself). In this particular embodiment, the respective second portion **509b** includes a volute shaped profile in the initial or predisposed configuration. Also for example, the respective third portion **509c** of the representative elongate member **504** shown in FIG. 5B includes a twisted profile about a respective twist axis **533** extending across at least part of the third portion **509c** of the elongate member **504**, the twist in the third portion **509c** arranged to rotationally offset (e.g., angularly rotated or twisted out of plane about an axis that may extend generally along a length of the elongate member prior to any distortion or deformation thereof) the respective second portion **509b** of the elongate member **504** from the respective first portion **509a** of the elongate member **504** along a portion of the length of the elongate member **504**. In this example embodiment of FIG. 5B, the respective first portion **509a** of the representative elongate member **504** includes a bent profile

51

about a respective bending axis **531**. It is understood that the number of elongate members **504** employed by the various embodiments of manipulable portion **502** associated with various ones of FIG. **5** is non-limiting.

In FIGS. **5A**, **5B**, and **5C**, each of the elongate members **504** is arranged in an arrangement having an initial or predisposed configuration in which each elongate member **504** is provided essentially in its distorted form. In various embodiments, the initial or predisposed configuration is associated with an initial, low, or lowest (potential) energy state. In various embodiments, each elongate member **504** is a resilient member and further distortion of various portions **509** of the elongate member **504** can increase spring or potential energy of the elongate member **504** and thereby bring it into a higher energy state. The (a) bent profiles of the respective first portions **509a**, (b) the twisted profiles of the respective third portion **509c**, or both (a) and (b) of various ones of the elongate members **504** in the initial or predisposed configuration may be arranged to fan or partially fan at least the respective second portions **509b** of various ones of elongate members **504** into a fanned array as shown, for example, in FIG. **5C**. It is noted, however, that various fanning angles **519** (only one called out in FIG. **5C**) may be achieved between a respective pair of the first and the second portions **509a**, **509b** by positional adjustments of the twist axis **533**, according to some embodiments.

In some embodiments, various ones of the elongate members **504** are physically or operatively coupled with at least one other elongate member **504** by at least one coupler. In FIG. **5C**, at least one coupler is arranged to couple at least the respective first portions **509a** of the elongate members **504** together in the initial configuration. Various couplers may be employed in these embodiments. For example, in embodiments where each of various ones of the elongate members **504** includes a flexible printed structure having a relatively large number of electrically conductive traces, a coupler that couples at least the side edges of the first portions **509a** may be well suited to avoid imposing undesired space constraints on the placement of the electrically conductive traces. In various example embodiments, additional couplers may also be employed to couple various other portions (e.g., portions **509**) of various ones of the elongate members **504** together. In this regard, as shown in FIG. **5C**, a control cable **513b** passes through openings at distal end portions of the elongate members **504** to operatively couple such distal end portions of elongate members **504** in some embodiments. A coupling system like that illustrated by control cable **513b** in FIG. **5C** may be used to couple other portions (e.g., various portions **509**) of elongate members **504** in some embodiments.

Referring back to FIG. **5A**, in various embodiments, the intermediate or elongated portion **510c** of the shaft **510** has a length **510d** extending between the proximal end **510a** and the distal end **510b** of shaft **510**. The length **510d** may be sized to position the proximal end **510a** at a location outside of a body when the distal end **510b** (or the manipulable portion **502**) is located in a bodily cavity within the body. In various embodiments associated with FIG. **5**, a housing **520** of the shaft member **500a** is physically or operatively coupled to shaft **510** at a location at least proximate the proximal end **510a** of the shaft **510**, the proximal end **512a** of the catheter sheath **512**, or both (e.g., at a location outside a body when the manipulable portion **502** is positioned at a desired location within a bodily cavity located in the body).

One or more control systems (e.g., one or more components of control system **322**, control system **545**, or both control system **322** and control system **545** described in this

52

disclosure) may be provided by housing **520** (e.g., in, on, or both in and on housing **520**). In this regard, the housing **520** may be referred to as a control system housing. Such housing **520** may be located at least proximate the proximal end **510a** of the shaft **510**.

Various actuator sets described in this disclosure may be provided by housing **520** (e.g., in, on, or both in and on housing **520**). For example, in some embodiments, at least (a) some of the shaft **510** (e.g., at least part of the proximal end **510a** of the shaft **510**), (b) some of the control element **513**, (c) some of one or more of the actuators described herein with respect to FIGS. **5R**, **5S**, **5W**, **7**, **8**, and **10**, (a) and (b), (a) and (c), (b) and (c), or (a), (b), and (c) may be enclosed within the housing **520**. The various actuator sets may, by way of non-limiting example, be part or all of such control system(s) and be configured to control or modulate, in response to user or other input, a size, shape, or both size and shape of various configurations of manipulable portion **502** (e.g., delivery and expanded or deployed configurations). One or more of the various actuator sets may be referred to as an actuator system, such that, for example, the actuator system is located, at least in part, in the housing **520**. An actuator system may, by way of non-limiting example, be operatively coupled to the manipulable portion **502** and configured to move or transition, in response to or under the control of user or other input, manipulable portion **502** between various configurations (e.g., delivery and expanded or deployed configurations). The actuator system may, by way of non-limiting example, be configured to control, in response to or under the control of user or other input (e.g., from a control system such as controller **324** or data processing device system **110**), various control elements employed by catheter system **500**. For example, at least some of these control elements may be controlled, e.g., by user or otherwise (e.g., from a control system such as controller **324** or data processing device system **110**) to selectively provide (a) a desired amount of force outputted by an actuator in the actuator system, (b) a desired duration of a force outputted by an actuator in the actuator system, or both (a) and (b) to manipulable portion **502**.

Control elements may include, by non-limiting example, control rods, control lines, control cables, Bowden cables, other force transmission components configured or arranged to selectively deliver force or energy outputted by an actuator to a particular device or structure (e.g., manipulable portion **502**). In some embodiments, a control element forms part of a bending system that operates on the manipulable portion **502** to bend at least some of the manipulable portion **502**. For example, the control element may be employed to transmit a bending force to the manipulable portion **502** to bend at least a part thereof.

In some embodiments, an actuator system includes at least a portion of one or more of the various actuators described herein (e.g., with respect to at least any one of the figures in FIGS. **5R**, **5S**, **5W**, **7**, **8**, and **10**). In this regard, in embodiments where the actuator system is controlled by a control system (e.g., from a control system such as controller **324** or data processing device system **110**), such control system is operatively coupled to the actuator system, for example, to control motion or other activation of at least a portion of the one or more of the actuators in the actuator system.

In various embodiments, housing **520** includes a cover **520a** that is moveable along a surface of housing **520** to provide access to an interior portion of housing **520**. In some of these various embodiments, cover **520a** is moveable to provide access (e.g., user access) to various actuators asso-

53

ciated with housing 520. In various embodiments, housing 520 may be directly handled by a user during a medical procedure in which catheter system 500 is employed. As shown in FIG. 5A, housing 520 may include at least part of an electrical coupling 521 which may in some embodiments allow for data, power, or both data and power communication with various transducers (e.g., transducers 506). Electrical coupling 521 may allow for electrical communication with (a) a controller (e.g., controller 324 or data processing device system 110) or (b) an energy source device system (e.g., energy source device system 340) or both (a) and (b).

As best shown in FIG. 5C, shaft 510 can include, in various embodiments, one or more lumens extending between the proximal end 510a (not shown in this figure) and the distal end 510b of shaft 510, the one or more lumens including at least a second lumen 511 (to be distinguished from the first lumen 512d of the catheter sheath 512). In various embodiments at least one control element is provided in the second lumen 511. For example, an elongated control element 513 is provided in second lumen 511 in FIG. 5C. In embodiments where the shaft 510 is within the first lumen 512d of the catheter sheath 512, the control element 513 within the second lumen 511 of the shaft 510 may also be considered to be within the first lumen 512d of the catheter sheath 512, because the shaft 510 is within the catheter sheath 512 in these embodiments. It is understood that additional or alternate control elements may be received in the second lumen 511 in other embodiments.

In various embodiments, control element 513 is physically coupled to the manipulable portion 502 to transmit force to the manipulable portion and includes multiple components or portions. For example, in FIG. 5C, control element 513 includes a sleeve 513a and a control cable 513b located, at least in part, in a lumen of the sleeve 513a. The control cable 513b may be physically coupled to the manipulable portion 502 to transmit force to the manipulable portion. Each of the cable 513b and the sleeve 513a may be located, at least in part, in the lumen 511 of the shaft 510. In some embodiments, sleeve 513a and cable 513b (and any sleeve and cable of a Bowden cable described herein) are moveable independently or separately with respect to one another to allow (a) the sleeve 513a to move independently or separately from the cable 513b to cause the sleeve 513a to slide over the cable 513b (e.g., during a first manipulation of the manipulable portion 502 to change a size, shape, or both thereof), and to allow (b) the cable 513b to move independently or separately from the sleeve 513a to cause the cable 513b to slide through the lumen of the sleeve 513a (e.g., during a second manipulation of the manipulable portion to change a size, a shape, or both thereof). This can occur, for example, when the at least a portion of the cable 513b received in the lumen of the sleeve 513a is translated in a direction that the lumen of the sleeve 513a extends along. In some embodiments, a portion of cable 513b and a portion of sleeve 513a are each translated concurrently (for example, in a direction that a portion of the lumen of the sleeve 513a extends along). In some embodiments, cable 513b is provided by a flexible control line (e.g., a flexible control line having a polymeric, metallic, or composite composition). In this regard, the control element 513 may be considered a flexible control element in some embodiments. In some embodiments, sleeve 513a is also flexible and can be bent (i.e., elastically or plastically) to have an arcuate form. In various embodiments, sleeve 513a comprises sufficient axial stiffness to withstand a particular compressive force, for example created by a tensioning of cable 513b. In various embodiments, sleeve 513a has a polymeric, metallic

54

or composite composition. For example, the present inventors have employed thin-walled stainless steel tubing in some embodiments.

In some embodiments, sleeve 513a and cable 513b form part of a Bowden cable. A Bowden cable is a generally flexible cable used to transmit force by the movement of an inner cable relative to a hollow outer cable housing (also sometimes referred to as a sleeve or sheath). The housing may be generally of composite construction, for example a tightly helically wound metallic wire sometimes lined with a friction reducing polymer. Typically, a first part of the cable extends outwardly from a first end of the sleeved housing, and a second part of the cable extends outwardly from a second end of the sleeved housing. The translational movement of the inner cable is most often used to transmit a pulling force, although push/pull cables are also employed. The cable housing provides the Bowden cable with compressive strength to resist buckling during a tensioning of the inner cable. The cable housing maintains a fixed separation with respect to the length of the inner cable so that displacing the inner cable relative to one end of the cable housing results in an equal displacement at the other end, regardless of the cable's path in-between. In FIG. 5C a portion 514 of cable 513b (i.e., also called part 514 in some embodiments) of elongated control element 513 extends or is located outwardly from an end 513a-1 of sleeve 513a and is physically coupled to the manipulable portion 502 at least by being physically coupled to one or more of the elongate members 504. In this regard, cable 513b (an example of a control element or an elongated control element) includes a distal end positionable outside of the distal end 512b of the catheter sheath 512 when a particular amount of the manipulable portion 502 is located outside of the distal end 512b of the catheter sheath 512. In embodiments such as those illustrated by FIG. 5C, cable 513b extends through a respective opening provided near the distal end 505 (not called out in FIG. 5C) of each of a majority of the elongate members 504 and terminates near the distal end 505 of another of the elongate members 504. In some embodiments, this arrangement couples distal end portions of the elongate members 504 and allows the distal ends 505 of the elongate members 504 to be drawn together in a purse string-like manner. In various embodiments, both the sleeve 513a and the cable 513b extend through the second lumen 511 to housing 520 (not shown in FIG. 5C). In various embodiments, (e.g., as described later in this disclosure) each of the sleeve 513a and the cable 513b extends through the second lumen 511 to a respective actuator provided by housing 520, which, in some embodiments, couples at least one of the respective actuators to the manipulable portion 502. In some embodiments, each of these respective actuators is operable to move a respective one of the sleeve 513a and the cable 513b independently or separately of the other of the sleeve 513a and the cable 513b. In some embodiments, each of these respective actuators is operable to move a respective one of the sleeve 513a and the cable 513b independently or separately of the other of the sleeve 513a and the cable 513b to cause translational movement of a portion of the cable 513b through a portion of the sleeve 513a or to cause translational movement of a portion of the sleeve 513a over a portion of the cable 513b. In FIG. 5C, cable 513b may be in a slackened configuration or a configuration having limited tension imposed on the cable 513b when the manipulable portion 502 is in the initial configuration.

In various embodiments, the body portion 512c of catheter sheath 512 has a length 512f (e.g., FIG. 5A) extending between the proximal end 512a and the distal end 512b and

sized and dimensioned to position manipulable portion **502** at a desired location outwardly from the distal end **512b**, when the shaft **510** has delivered the manipulable portion **502** through the first lumen **512d** (i.e., along a path extending from the proximal end **512a** toward the distal end **512b** of catheter sheath **512**), such that the proximal end **510a** of the shaft **510** is positioned at a desired location with respect to the proximal end **512a** of the catheter sheath **512**. Positioning indicia set **523a** may be provided on a visible surface of the elongated portion **510c** of shaft **510** proximate the proximal end **510a**, to provide a user with a visual indication of a distance between a location on the shaft **510** (e.g., proximal end **510a**) and a location on the sheath **512** (e.g., the proximal end **512a**) as the two locations are advanced with respect to one another to reduce a distance therebetween (for example, during an advancement of manipulable portion **502** toward a bodily cavity as the manipulable portion **502** is moved through first lumen **512d**). Positioning indicia set **523b** may be provided on a visible surface of the elongated portion **510c** of shaft **510** proximate the distal end **510b**, to provide a user a visual indication of a distance between a location on the shaft **510** (e.g., the distal end **510b**) and a location on the sheath **512** (e.g., the proximal end **512a**) as the two locations are advanced with respect to one another to increase a distance therebetween (for example during a retraction of manipulable portion **502** away from a bodily cavity as the manipulable portion **502** is moved through first lumen **512d**).

The positioning indicia sets **523a** and **523b** can visually indicate a magnitude of their respective shaft **510**-to-catheter sheath **512** spacing in various ways. For example, in some embodiments associated with FIG. 5A, the spacing between successive pairs of indicia in each one of the respective sets **523a**, **523b** is reduced (i.e., as compared to the pair of indicia immediately preceding the successive pair) to indicate a reduction in the magnitude of the respective shaft **510**-to-catheter sheath **512** distance. The positioning indicia sets **523a**, **523b** can be employed by a user to determine an approach of an end-of-travel condition between the shaft **510** and the catheter sheath **512**.

In some embodiments, catheter sheath **512** includes a steerable portion **512e**. In FIG. 5A, steerable portion **512e** is located at least proximate to distal end **512b** but may be located at other locations in other embodiments. The steerable portion can be caused to bend or deflect in a desired manner by user or other (e.g., data processing device system) operation of a catheter sheath actuator **516**. Steering of the steerable portion **512e** may be motivated by various reasons including assisting delivery of the catheter sheath **512** through a bodily opening extending along a tortuous path to the bodily cavity. Various suitable catheter sheath steering mechanisms are known in the art and are not elaborated in further detail in this disclosure. In some embodiments, catheter sheath **512** includes a flushing portion **524** that includes various ports **524a**, **524b** configured to provide an inlet or outlet, or both an inlet and outlet for a fluid (e.g., saline) to be introduced to reduce occurrences of gas (e.g., air) that may be present or sometimes entrapped within first lumen **512d**. In some embodiments, flushing portion **524** is detachable from catheter sheath **512**. In various embodiments, an extension or projection **528** extends from a location proximate a first one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510**. In some embodiments, projection **528** extends beyond the first one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510** at least when a part of the shaft **510** is received in first lumen **512d**.

In some embodiments, projection **528** extends outwardly from the first one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510** toward one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510** other than the first one, at least when part of the shaft **510** is received in first lumen **512d**. In some embodiments, a receiver **529** located, at least in part, in the housing **520**, and sized to matingly receive at least a portion of the projection **528**, is provided at a location proximate a second one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510**. In some of these various embodiments, the projection **528** and the receiver **529** are configured to matingly engage at least when a first amount of part of the shaft **510** is received in the first lumen **512d** of the catheter sheath **512**, but to not matingly engage at least when a second amount of the part of the shaft is received in the lumen of the catheter sheath, the second amount being a non-zero amount in some embodiments. For example, projection **528** may form part of a male component while receiver **529** forms part of a female component sized to mate with the male component. In some embodiments, the projection **528** and the receiver **529** are configured or arranged to additionally matingly engage the catheter member **512** to the shaft **510** at least when part of the shaft **510** is matingly received in the first lumen **512d** of the sheath **512**. In various embodiments, the projection **528** includes a length (e.g., a longitudinal length) that extends from a location at least proximate the first one of the proximal end **512a** of the catheter sheath **512** and the proximal end **510a** of the shaft **510** to an end **528b** of the projection **528**, the end **528b** of the projection **528** configured to be received first in the receiver **529**, as compared to other parts of the projection **528** when the projection **528** is inserted into receiver **529**. In various embodiments, projection **528** has a length **528a** (called out in FIG. 5D) that is different than the longitudinal length **510d** of the shaft **510**. In this regard, in some embodiments, the longitudinal length **510d** of the shaft **510** is greater than the longitudinal length **528a** of the projection **528**.

It is noted that in some embodiments, the first one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510** is a same one as the second one of the proximal end **512a** of catheter sheath **512** and the proximal end **510a** of shaft **510** (for example, when projection **528** and receiver **529** are integrated into or form part of a plunger assembly located on one of the shaft **510** (or shaft member **500a**) and the catheter sheath **512** (or catheter sheath member **500b**). FIGS. 5T, 5U, and 5V are various side elevation views of a catheter system **501** comprising a shaft **510-1** physically coupled to a housing **520-1**, the shaft **510-1** sized and dimensioned for insertion into a lumen of a catheter sheath **512-1** according to some embodiments. In particular, FIGS. 5T, 5U, and 5V show a positioning of shaft **510-1** into the lumen of catheter sheath **512-1** at three successive points in time (from FIG. 5T to FIG. 5V, or vice versa). Catheter system **501** includes a plunger assembly **530** that includes a projection **528-1** received in a receiver **529-1**, each of the projection **528-1** and receiver **529-1** provided at least in part in housing **520-1** (i.e., shown partially sectioned) at a location proximate a proximal end **510a-1** of the shaft **510-1**. In FIG. 5T, shaft **510-1** has been inserted into the lumen of catheter sheath **512-1** by an amount insufficient to cause an end of projection **528-1** to engage with the catheter sheath **512-1** (e.g., at a location proximate a proximal end **512a-1** of the catheter sheath **512**). As the amount of the shaft **510-1** inserted into the lumen of catheter sheath **512** increases, the distance between the proximal end **512a-1** of catheter sheath

57

512-1 and the proximal end 510a-1 of the shaft 510-1 decreases and causes engagement between the projection 528-1 and the catheter sheath 512-1 to occur. As the amount of the shaft 510-1 inserted into the lumen of catheter sheath 512 increases, the distance between the proximal end of catheter sheath 512-1 and the proximal end 510a-1 of the shaft 510-1 decreases and causes increasing amounts of projection 528-1 to be received in receiver 529-1 as shown in FIGS. 5U and 5V. In some embodiments, a biasing device such as a spring provides a restoring force sufficient to move projection 528-1 to its extended configuration as the distance between the proximal end of catheter sheath 512-1 and the proximal end 510a-1 of the shaft 510-1 increases.

In other embodiments, the first one of the proximal end 512a of catheter sheath 512 and the proximal end 510a of shaft 510 (i.e., the "first one" being the end proximate the location from which the extension or projection 528 extends) is different than the second one of the proximal end 512a of catheter sheath 512 and the proximal end 510a of shaft 510 (i.e., the "second one" being the end proximate the location at which the receiver 529 is provided). For example, in some embodiments associated with FIG. 5A, the projection 528 is located at least proximate the proximal end 512a of catheter sheath 512, the projection 528 sized and dimensioned to be matingly received in at least a receiver 529 provided, in some embodiments, at a location at least proximate the proximal end 510a of shaft 510 (e.g., in the housing 520 in FIG. 5A) at least when a part of shaft 510 is received in first lumen 512d. In some of the embodiments associated with FIG. 5A, a longitudinal axis of the first lumen 512d (e.g., when catheter sheath 512 assumes a straightened form) is not coaxial with a longitudinal axis of first projection 528. In some of the embodiments associated with FIG. 5A, a longitudinal axis of the first lumen 512d (e.g., when catheter sheath 512 assumes a straightened form) is not coaxial with a longitudinal axis along which projection 528 is moveable within receiver 529. In some of the embodiments associated with FIG. 5A, the manipulable portion 502 is arranged to not be inserted into the receiver 529 when the manipulable portion 502 is delivered through first lumen 512d of the catheter sheath 512, e.g., to a bodily cavity. In some embodiments, the receiver 529 and first lumen 512d may be coaxially arranged when the manipulable portion 502 is delivered outwardly from the distal end 512b of catheter sheath 512. In some embodiments, the projection 528 is coupled to, or forms part of, shaft member 500a. In some embodiments, the receiver 529 is coupled to, or forms part of, sheath member 500b. In some embodiments, the projection 528 is distinct from shaft member 500a.

FIGS. 5D, 5E, and 5F are various side elevation views of a positioning of shaft 510 into the first lumen 512d (not called out in these figures) of catheter sheath 512 at three successive points in time (from FIG. 5D to FIG. 5F, or vice versa). At least one portion of the catheter system 500 (e.g., manipulable portion 502, not shown in FIGS. 5D, 5E and 5F) is selectively reconfigured according to various embodiments during at least some of these points in time. It is understood that in each of FIGS. 5D, 5E and 5F, the distal end 510b (not shown in FIGS. 5D-5F) of shaft 510 has been introduced into the first lumen 512d (not shown in FIGS. 5D-5F) of catheter sheath 512 and is advanced from the proximal end 512a of the catheter sheath 512 toward the distal end 512b (not shown in FIGS. 5D-5F) of catheter sheath 512. As best shown in FIG. 5A, in some embodiments, shaft 510 includes a longitudinal length 510d extending between the proximal and distal ends 510a, 510b of shaft

58

510, the longitudinal length 510d of the shaft being different (e.g., greater in FIG. 5A) than the longitudinal length 528a of projection 528.

In some embodiments associated with various ones of FIG. 5, a first particular amount of the longitudinal length 528a of the first projection 528 is located in receiver 529 when a second particular amount of the longitudinal length 510d of shaft 510 is located inside first lumen 512d of the catheter sheath 512, the first particular amount of the longitudinal length 528a of the first projection 528 being less than the second particular amount of the longitudinal length 510d of shaft 510. In various embodiments, the projection 528 and receiver 529 are configured to matingly engage at least when a first amount of part of the shaft 510 is received in the first lumen 512d (e.g., as shown respectively by each of FIGS. 5E and 5F), and the projection 528 and receiver 529 are configured not to matingly engage at least when a second amount of the part of the shaft 510 is received in the first lumen 512d (e.g., as shown in FIG. 5D). In some of these various embodiments, the first amount is different (e.g., greater) than the second amount, and in some embodiments, the first amount and the second amount are each an amount of the longitudinal length 510d of the shaft 510.

In some embodiments, projection 528 and receiver 529 are configured to matingly engage when shaft 510 is not received in first lumen 512d. This circumstance can occur in some embodiments, when projection 528 and receiver 529 form part of a plunger assembly (e.g., plunger assembly 530) provided on one of shaft 510 and catheter sheath 512. This circumstance can occur in some embodiments that are the same or similar to that shown in FIG. 5A where a particular positioning and orientation between shaft 510 and catheter sheath 512 allow for a mating between projection 528 and receiver 529 without the shaft 510 being received in first lumen 512d.

In FIG. 5D, projection 528 extending from the proximal end 512a of catheter sheath 512 has not been received in the first receiver 529 provided in the housing 520, while various amounts of the projection 528 have been received in receiver 529 in FIGS. 5E and 5F, the amounts varying (e.g., increasing) with the advancement of shaft 510 through first lumen 512d. In the configuration evolution from FIG. 5D, to FIG. 5E, and to FIG. 5F, manipulable portion 502 (not shown in FIGS. 5D, 5E and 5F) is advanced through the first lumen 512d from the proximal end 512a of the catheter sheath 512 toward the distal end 512b of catheter sheath 512. A control system or actuator system (e.g., one or more components of control system 322 or system 545, possibly including one or more of the components of at least FIG. 5R, 5S, 5W, 7, 8, or 10) may respond to or be controlled by varying amounts of the length 528a of the projection 528 being within the receiver 529 and alter aspects of the manipulable portion 502 in response to or under the control of these varying amounts. For example, the control system or actuator system physically or operatively coupled to the manipulable portion 502 may respond to or be controlled by varying amounts of the length 528a of projection of 528 being within receiver 529 by varying force transmitted to the manipulable portion 502 in accordance with the varying amounts of the length 528a of projection of 528 being within receiver 529, e.g., while the distal end of the manipulable portion 502 advances outwardly from the distal end 512b of the catheter sheath 512 along an arcuate or coiled path (for instance, FIGS. 5H, 5I, 5J).

As shown in FIG. 5G, the respective first portions 509a (only one called out) of the elongate members 504 (only one called out) are arranged with respect to one another front

59

surface **518a**-toward-back surface **518b** in a first direction represented by arrow **530a** in a first stacked array **515a** (see, e.g., proximal end **307** in FIG. 3A for a closer look at such a first stacked array) sized and shaped to be delivered through first lumen **512d** of catheter sheath **512** when a portion of the catheter system **500** (e.g., manipulable portion **502**) is in a delivery configuration also known as a first or unexpanded configuration in some embodiments. In various embodiments, manipulable portion **502** is in the delivery configuration as it is delivered through the first lumen **512d** as described above, for example, in regards to FIGS. 5D, 5E, and 5F. As shown in FIG. 5G, the respective second (intermediate) portions **509b** (only one called out) of the elongate members **504** are arranged with respect to one another front surface **518a**-toward-back surface **518b** in a second direction as represented by arrow **530b** in a second stacked array **515b** sized to be delivered through the first lumen **512d** when the portion of the catheter system **500** is in the delivery configuration. In various embodiments, the first direction (i.e., arrow **530a**) and the second direction (i.e., arrow **530b**) are non-parallel directions at least when the arrayed elongate members **504** assume a straightened form.

In various embodiments, the elongate members **504** of the manipulable portion **502** are arranged within catheter sheath **512** such that each elongate member **504** is to be advanced distal end **505** first into a bodily cavity. In various embodiments, the elongate members **504** are arranged within catheter sheath **512** such that each elongate member **504** is to be advanced out distal end **505** first from the distal end **512b** of catheter sheath **512**. In some embodiments, manipulable portion **502** includes a first or proximal portion **508a** and a second or distal portion **508b**, each of these portions comprising a respective part of each of at least some of the elongate members **504**. In some embodiments, the proximal and the distal portions **508a**, **508b** include respective portions of elongate members **504**. In some embodiments, the manipulable portion **502** is arranged to be delivered second or distal portion **508b** first through the lumen **512d** of the catheter sheath **512** into a bodily cavity when the manipulable portion **502** is delivered in the unexpanded or delivery configuration as shown, e.g., in FIG. 5G.

Notably, as used herein, the term “stacked” does not necessarily require the elongate members **504** rest directly or even indirectly upon one another, but rather refers to an ordered arrangement which may include spaces or gaps between immediately adjacent or most immediate neighboring pairs of elongate members **504**. It is also noted that while illustrated in FIG. 5G as a plurality of substantially parallel stacked plates or strips, the elongate members **504** need not be perfectly rigid, so there may be some flex, sag, or curvature even when the catheter sheath **512** is essentially straight. It is further noted that in use, the catheter sheath **512** may curve or even twist to follow a bodily lumen. The elongate members **504** may adopt or conform to such curvatures or twists as the elongate members **504** are advanced through catheter sheath **512**. In either of these situations, the elongate members **504** generally maintain the relative positions to one another as a stacked arrangement.

In various embodiments, the respective first, second, and third portions **509a**, **509b** and **509c** (only one of each called out in FIG. 5G) of various ones of the elongate members **504** have been stressed into a higher energy state illustrated in FIG. 5G, as compared to a lower energy state shown, e.g., in FIGS. 5A, 5B, and 5C. In various embodiments, the respective second portions **509b** of various ones of the elongate members **504** in the initial or predisposed configuration (e.g., as shown in FIGS. 5A, 5B, and 5C) have been

60

stressed into a higher energy state suitable for unbending or uncoiling them sufficiently enough to allow the elongate members **504** to be delivered through catheter sheath **512** in the delivery configuration as shown in FIG. 5G. In various embodiments, at least one of the respective first portions **509a** and the third portions **509c** of each of various ones of the elongate members **504** has been stressed into a higher energy state by un-fanning at least the second portions **509b** of the elongate members **504** sufficiently to allow the elongate members **504** to be introduced into, and delivered through catheter sheath **512**. In some of these embodiments, potential energy is imparted to the various elongate members **504** in the delivery configuration by the higher energy state, the potential energy sufficient to return the arrangement of elongate members **504** generally back toward a lower energy state when released from the confines of catheter sheath **512**.

In some example embodiments, the arrangement of elongate members **504** is stressed into a higher energy state by retracting the arrangement of elongate members **504** into at least a portion of catheter sheath **512** prior to inserting catheter sheath **512** into a body. For example, in various embodiments the arrangement of elongate members **504** is stressed into a higher energy state by retracting the arrangement of elongate members **504** at least into the flushing portion **524** of catheter sheath **512**. In some of these various embodiments, the flushing portion **524** is detached from the remainder of the catheter sheath **512** when the arrangement of elongate members **504** is retracted into the flushing portion **524** with the flushing portion **524** subsequently attached or reattached to the remainder of the catheter sheath **512** after the retraction. This technique may advantageously allow for a more efficient operation as the arrangement of elongate members **504** need not be retracted through the entirety of the catheter sheath **512**.

In some embodiments, the arrangement of elongate members **504** is stressed into a higher energy state by uncoiling the elongate members **504** and inserting the arrangement of elongate members **504** into catheter sheath **512**. In some embodiments, the arrangement of elongate members **504** is reconfigured from the initial or predisposed configuration shown in FIGS. 5A, 5B, 5C, which is typically provided or calibrated at the time of manufacturing, to the delivery configuration shown in FIG. 5G at a point of use. In some embodiments, the arrangement of elongate members **504** is reconfigured from the initial or predisposed configuration shown in FIGS. 5A, 5C to the delivery configuration shown in FIG. 5G at a place of manufacture, assembly, or distribution. In various embodiments, various devices including various guides or manipulators may be employed to reconfigure the arrangement of elongate members **504** from the initial or predisposed configuration shown in FIGS. 5A, 5C to the delivery configuration shown in FIG. 5G. In some of these various embodiments, these devices form part of catheter system **500** (e.g., flushing portion **524**). In some embodiments, the devices are extraneous to catheter system **500**. The higher energy states may be controlled to not cause damage to portions of catheter system **500** during delivery through catheter sheath **512**. In FIG. 5G, cable **513b** is extended along the elongate members **504** in the delivery configuration. In various embodiments, cable **513b** is delivered through first lumen **512d** when the elongate members **504** are advanced in a delivery configuration toward a bodily cavity. In various embodiments, cable **513b** is drawn through first lumen **512d** by the manipulable portion **502** as the manipulable portion **502** is advanced in a delivery configuration toward a bodily cavity.

61

FIGS. 5H, 5I, and 5J are various side elevation views of various respective parts of manipulable portion 502 positioned at three successive points in time as each respective part of the manipulable portion 502 or structure 502a thereof is advanced outwardly from the confines of the first lumen 512d (not called out in these figures) of catheter sheath 512 (i.e., from the distal end 512b). These figures illustrate coiling and uncoiling of the manipulable portion 502 during deployment and retraction, respectively, of the manipulable portion.

FIG. 5J shows a portion of the catheter system 500 including the plurality of elongate members 504 (two called out) positioned in an expanded configuration also referred to as a second or bent configuration. In FIG. 5J, the manipulable portion 502 (or at least an elongated part thereof) has a volute or coiled shape, e.g., after a control system or actuator system (e.g., as described herein) that is operatively or physically coupled to the manipulable portion 502 varies a size, shape, or both size and shape of at least part of the manipulable portion extending outside of the distal end 512b of the catheter sheath 512 to, at least in part, cause the distal end of the manipulable portion to move along a first trajectory. In FIG. 5J, the respective second portions 509b (only one called out) of various ones of the elongate members 504 have cleared the confines of first lumen 512d (not called out) while other portions of the elongate members 504 remain within the confines of first lumen 512d. In various embodiments, each of at least the respective second portions 509b of each elongate member 504 is curved about a respective bending axis 534 (i.e., one represented by symbol "X") into an arcuate stacked array 532. Each bending axis 534 extends in a direction having a directional component transversely oriented to the respective longitudinal length of the respective elongate members 504. In various embodiments, each of the respective second portions 509b of various ones of the elongate members 504 in the arcuate stacked array 532 is coiled about a respective bending axis 534 into a coiled stacked array. In various embodiments, each respective second portion 509b is bent to have a scroll or volute shaped profile. In various embodiments, each second portion 509b is arranged to have a curvature that varies at least once along the respective length of the elongate member 504. In some embodiments, when positioned in the second or bent configuration, a first portion 521a of the front surface 518a (only one called out) of the respective second portion 509b of each elongate member 504 is positioned diametrically opposite to a second portion 521b of the front surface 518a in the volute shaped structure 502a. When positioned in the second or bent configuration, the coiled arrangement of elongate members 504 is sized, shaped, or both sized and shaped too large for delivery through the first lumen 512d, at least in a direction toward the bodily cavity. In this regard, it can be said that when the coiled arrangement of elongate members 504 is in the second or bent configuration (e.g., FIG. 5J), the manipulable portion 502 comprises a coiled form in an expanded configuration.

In various embodiments, the respective second portions 509b of various ones of the elongate members 504 are pre-formed to autonomously bend when the second portions 509b are advanced outwardly from the confines of first lumen 512d. As the respective second portions 509b are advanced from the confines of first lumen 512d, they are urged or biased to seek their low energy state (e.g., their initial coiled configuration). In various embodiments, the respective distal ends 505 of various ones of the elongate members 504 (only one called out in each of FIGS. 5H, 5I, and 5J) move along a trajectory that follows a coiled path

62

(e.g., a path that curves back on itself) during the advancement of various parts of manipulable portion 502 outwardly from the confines of first lumen 512d. In various embodiments, the coiled path makes at least one full turn. In some embodiments, at least part of the coiled path may extend along a volute path. In some embodiments, manipulable portion 502 or structure 502a thereof has a distal end (i.e., the same or different than a distal end 505 of an elongate member 504) configured to be delivered first, with respect to other parts of the manipulable portion 502 through the first lumen 512d or outwardly from the distal end 512b of catheter sheath 512.

In various embodiments, the respective second portions 509b of various ones of the elongate members 504 are pre-formed to autonomously coil as they are advanced into a bodily cavity in a manner that may advantageously reduce physical interactions between at least the distal end 505 of the elongate members 504 and an interior tissue surface within the bodily cavity (not shown in FIG. 5 but may be exemplified by left atrium 204 of FIG. 2) into which they are deployed. In various embodiments, the elongate members 504 are arranged to continuously bend or curl to move at least the respective distal ends 505 of the elongate members away from an interior tissue surface within a bodily cavity into which they are advanced. A reduction of contact and other physical interaction of the elongate members 504 with an interior tissue surface within a bodily cavity during the advancement may reduce occurrences of, or the severity of, damage inflicted to various tissue structures (i.e., especially damage caused by the distal end 505 of an elongate member 504 which may catch on various tissue structures during the advancement). In some embodiments, the arcuate stacked array 532 is arranged to have a predetermined size that will allow the arcuate stacked array 532 to be positioned within a bodily cavity with at most relatively minor amounts of contact with an interior tissue surface within the bodily cavity.

FIGS. 5H, 5I, and 5J show various interactions between a portion of control element 513 (e.g., cable 513b) and the manipulable portion 502 (e.g., structure 502a) as various respective parts of the manipulable portion 502 or structure 502a thereof are advanced outwardly from the confines of first lumen 512d. For example, FIGS. 5H, 5I, and 5J show various interactions between the part or portion 514 (FIG. 5C) of cable 513b located outside the distal end 512b of catheter sheath 512 and the manipulable portion 502 (e.g., structure 502a) as various respective parts of the manipulable portion 502 or structure 502a thereof are advanced outwardly from the confines of first lumen 512d. In some embodiments, a control system or actuator system (e.g., as described herein) responds to or is controlled by relative movement between shaft 510 and catheter sheath 512, and may control one or more actuators to cause these interactions. In some embodiments, a control system (e.g., from a control system such as controller 324 or data processing device system 110) is operatively coupled to an actuator system and is operable to control activation of one or more actuators of the actuator system in response to the relative movement between shaft 510 and catheter sheath 512. For example, in some embodiments, at least a portion of at least one actuator or modulation actuator (e.g., actuator 546, some other actuator or actuator set, or a portion of at least one of these actuators) physically or operatively coupled to a control element (e.g., 513) is moveable in each of a first direction and a second direction different than the first direction. In some embodiments, movement of at least the portion of the actuator (e.g., modulation actuator) in the first

63

direction may accompany an increase in an amount of manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512** (e.g., as shown by the sequence of FIGS. **5H**, **5I**, and **5J**), e.g., as the shaft **510** is moved distally through the catheter sheath **512**. In some embodiments, movement of at least the portion of the actuator (e.g., modulation actuator) in the second direction may accompany a decrease in an amount of manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512** (e.g., as shown by the sequence of FIGS. **5J**, **5I**, and **5H**), e.g., as the shaft **510** is moved proximally through the catheter sheath **512**.

In various embodiments, it may be important to prevent tension levels in various control elements (e.g., cable **513b**) from reducing below certain threshold levels during the outward advancement of the various respective parts of the manipulable portion **502** or structure **502a** thereof from the confines of first lumen **512d**. For example, reduction of tension in the cable **513b** to a level where slack develops in the cable member **513b** as parts of the manipulable portion **502** or structure **502a** are advanced outwardly from the confines of the first lumen **512d** of catheter sheath **512** may lead to various undesired conditions. In some cases, if sufficient slack in cable **513b** results, portions of cable **513b** may become wrapped, or otherwise entangled with the manipulable portion **502** and interfere with, or restrict a current or subsequent manipulation or deployment of the manipulable portion **502** (e.g., a subsequent manipulation or deployment as shown in FIGS. **5L-1**, **5L-2**, **5M-1**, **5M-2**, **5N**, **5O**, **5P** and **5Q**). Maintaining a desired tension on cable **513b** can be complicated when the elongate members **504** are advanced outwardly from the confines of first lumen **512d** along a path that requires both an advancement of portions of the cable **513b** from the first lumen **512d** and a subsequent retraction of portions of the cable **513b** into the first lumen **512d** during the movement along the path. For example, the coiled path that a distal end of the manipulable portion **502** follows as the manipulable portion **502** is advanced outwardly from the confines of first lumen **512d** of the catheter sheath **512** (e.g., as shown in FIGS. **5H**, **5I** and **5J**) may require an advancement of various portions of the cable **513b** from the first lumen **512d** and a subsequent retraction of various portions of the cable **513b** into the first lumen **512d** when some desired level of tension is required in cable **513b** (e.g., a level of tension sufficient to reduce occurrences of slackness in the cable **513b**). In various embodiments, modulation of a size, a shape, or both, of the manipulable portion **502** or structure **502a** thereof occurs at least in a state where at least a part of the manipulable portion **502** or structure **502a** thereof and a part of the control element **513** (e.g., cable **513b**) extends outside the distal end **512b** of the catheter sheath **512**. In some of these embodiments, a length of the part of the control element **513** is required to increase and then subsequently decrease during or throughout the modulation of the manipulable portion **502** or structure **502a**. In some of these various embodiments, the manipulable portion **502** or structure **502a** is sized or shaped during or throughout the modulation to have a size or shape sufficient to limit or restrict movement of at least the part of the manipulable portion **502** or structure **502a** through the first lumen **512d**.

FIG. **6** is a graph that includes a data set (i.e., represented by plot **600**) measured by some of the present inventors using a device that is the same or similar in construction to the manipulable portion **502** shown in FIG. **5**. The device includes a structure comprised of a stacked array of resilient elongate members approximately 240 millimeters in length

64

and pre-shaped to autonomously coil as the elongate members are advanced outwardly from the confines of a catheter lumen along which the device has been advanced (e.g., in a manner the same or similar to embodiments previously described with respect to FIGS. **5H**, **5I**, and **5J**). Plot **600** represents a required movement of a control line physically coupled to the distal ends of the device elongate members (i.e., the same or similar to cable **513b**) as the elongate members are positioned at different locations outwardly from the distal end of the catheter sheath as the elongate members autonomously bend to follow a coiled path upon advancement from the confines of the catheter sheath. The horizontal axis of the FIG. **6** graph is associated with an amount that a distal end of the structure (e.g., a distal end of at least one of the elongate members, such as distal end **505**) travels along a path that extends outwardly from a distal end of the catheter sheath while the vertical axis is associated with an amount of the control line that is metered during the movement along the path in accordance with various embodiments.

As used in this disclosure, the word “meter” means to supply or provide in a measured or regulated amount. In this regard, the metering of a control line (e.g., control cable **513b** or other elongated control element or portion thereof) can occur in different directions. For example in some embodiments, the control line can be caused (e.g., by one or more of the actuators **540a**, **540b**, **546** in FIG. **7**) to be metered or to move along a path with a controlled or regulated rate in a first direction (e.g., an action associated with “take-up” of the control line) suitable to reduce or decrease an amount of at least a portion of the control line (e.g., control cable **513b**) located outside a distal end (e.g., distal end **512b**) of the catheter sheath (e.g., catheter sheath **512**) during one of (a) a transition toward or to an expanded configuration of a manipulable portion (e.g., manipulable portion **502**) and (b) a transition toward or to a delivery configuration of the manipulable portion (e.g., manipulable portion **502**). In some embodiments, the control line can be caused (e.g., by one or more of the actuators **540a**, **540b**, **546** in FIG. **7**) to be metered or to move along a path with a controlled or regulated rate in a second direction (e.g., an action associated with “play-out” of the control line) suitable to increase an amount of at least a portion of the control line (e.g., control cable **513b**) located outside a distal end (e.g., distal end **512b**) of the catheter sheath (e.g., catheter sheath **512**) during the other of (a) and (b), or which can result in a relatively larger portion of the control line being available for extension outwardly from a distal end of the sheath.

In various embodiments, metering during play-out can reduce tension in the control line, sometimes to the point of imparting slackness in the control line. In some of these various embodiments, metering during play-out may allow increased amounts of the control line to be pulled outwardly from the distal end of the catheter sheath (for example by a release of stored potential energy in manipulable portion **502**). In some embodiments, metering during take-up can increase tension in the control line. It is noted that, in some circumstances, slack in the control line can exist during some part of a take-up procedure. For example, slack in cable **513b** may arise if the metering rate during take-up is insufficient to take up a portion of the cable **513b** that extends outwardly from the distal end **512b** of sheath **512** with a rate appropriate for the advancement of manipulable portion **502** from the distal end **512b** of sheath **512** along a coiled trajectory as shown in FIGS. **5H**, **5I** and **5J**. In various embodiments, the control line is metered with a rate that is dependent on a rate in which the distal end of the structure

65

(e.g., structure **502a**) advances outwardly from the distal end of the catheter sheath or advances inwardly into the distal end of the catheter sheath.

A portion **600a** of plot **600** shows that the control line is advanced outwardly from the distal end of the catheter sheath up to about a point where the stacked elongate members have been initially advanced outwardly from the distal end of the catheter sheath by approximately 50 mm along the path (e.g., in a manner that is the same or similar to that shown in FIG. 5H). In various embodiments, the control line is not actively metered and the control line may be advanced outwardly from the catheter sheath as the stacked array of elongate members pulls the control line outwardly during this initial advancement. Any slack in the control line may be taken up at least in part during this initial advancement. Further advancement along the path (i.e., from 50 mm up to about 170 mm) of the stacked elongate members outwardly from the distal end of the catheter sheath requires, in these embodiments, that the control line be taken-up to cause a portion of the control line to be retracted back into the distal end of the catheter sheath. In particular, portion **600b** of plot **600** is associated with an amount of the control line, in these embodiments, to be taken up without imparting particular force on the advanced portion of the elongate members extending outwardly from the distal end of the catheter sheath, the particular force sufficient to noticeably move the advanced portion of the elongate members away from their low potential energy state. It is noted that force transmitted to the elongate members by the control line can cause bending of the elongate members that in turn can impart potential or spring energy to the elongate members. It is understood that if an amount of control line taken-up between the 50 mm and 170 mm points on the horizontal axis is less than that required by plot **600** (i.e., below portion **600b**), then slack in the control line may exist, which may in turn, lead to various undesired results.

In part **600c** of plot **600**, the control line is controlled in accordance with a further movement of the coiled structure outwardly from the distal end of the catheter sheath according to various embodiments (for example as shown in FIGS. 5C, 5L-1, 5L-2). It is understood that different plots will result for other devices having different dimensions or different configurations, and the plot **600** is only presented by way of non-limiting example.

Ideally, in some embodiments, the take-up of the control line of the device described above in conjunction with FIG. 6 should occur above the “minimal” take-up amount specified by the portion **600b** of plot **600** to increase the likelihood that the control line does not slacken during the advancement of the device outwardly from the confines of the catheter sheath.

FIG. 6 includes a line **602** associated with a particular control line metering action employed according to some embodiments. Portion **602a** of line **602** is associated with a condition in which the control line is not taken up as the stacked elongate members are initially advanced outwardly from the distal end of the catheter sheath about 40 mm along a deployment path. During an additional or subsequent advancement of the stacked elongate members outwardly from the distal end of the catheter sheath along the deployment path, the control line is taken up or metered with a first rate (i.e., associated with the portion **602b** of line **602**) to cause a portion of the control line to be retracted inwardly into the distal end of the catheter sheath during a first part of the take-up. In FIG. 6, this first part of the control line take-up occurs when the stacked elongate members have

66

been advanced between 40 mm and 90 mm along the deployment path outwardly from the distal end of the catheter sheath. During further advancement of the stacked arrangement of the elongate members outwardly from the distal end of the catheter sheath, the control line is taken up or metered with a second rate (i.e., associated with the portion **602c** of line **602**) during a second part of the take-up. In FIG. 6, this second part of the control line take-up occurs when the stacked elongate members have been advanced between 90 mm and 200 mm along the deployment path outwardly from the distal end of the catheter sheath. In various embodiments, the first metering rate is different than the second metering rate. For example, in FIG. 6, the first metering rate is twice the second metering rate as indicated by the difference in the slopes of line portions **602b** and **602c**. In this regard, in some embodiments, the first metering rate may be referred to as a “2× rate”, and the second metering rate may be referred to as a “1× rate”. Different rates may be employed in other embodiments. In various embodiments, metering of the control line, with the first rate, the second rate or each of the first and second rates occurs along a particular direction that is relative to, or respective with, a reference frame that is provided by a portion of the catheter device (e.g., the catheter shaft to which the manipulable portion is coupled) that is moveable with respect to the catheter sheath. In various embodiments, metering of the control line, with the first rate, the second rate or each of the first and second rates, may lead to different respective rates of movement of the control line with respect to a reference point on the catheter sheath (e.g., a distal end of the catheter sheath).

A large portion of the control line take-up represented by portion **602b** of line **602** is above the “minimum” threshold provided by the portion **600b** of plot **600** and occurrences of slack in the control line are reduced when the control line is metered in accordance with line **602**. The different metering rates represented by portions **602b**, **602c** of line **600** may be motivated by different reasons. For example, with reference to FIG. 5I, a first (e.g., a relatively higher) take-up rate similar to the first rate represented by the slope of portion **602b** in FIG. 6 may be employed to ensure proper retraction of control cable **513b** since the manipulable portion **502** is being further advanced along a portion of its trajectory outwardly from the distal end **512b** of the catheter sheath **512** (i.e., as compared between FIGS. 5H and 5I) along a path that coils or curls back on itself and may thus benefit from a relatively rapid take-up of the cable **513b**. It is noted that in various embodiments associated with FIG. 5, the manipulable portion **502** autonomously coils as the manipulable portion **502** is advanced outwardly from the confines of the first lumen **512d**. As previously described above in this disclosure, the autonomous coiling may be motivated by different reasons including reducing occurrences of undesired contact between a distal end **505a** (e.g., provided by at least one of the distal ends **505** in some embodiments) of the manipulable portion **502** and a tissue surface defining a bodily cavity into which the manipulable portion **502** is advanced. The first take-up rate can be defined or predetermined to cause the take-up of the cable **513b** to be sufficient to additionally bend the manipulable portion **502** or structure **502a** thereof to cause portions thereof to assume a smaller radius of curvature than they would normally have from their autonomously formed shapes. This situation can in turn result in an advancement trajectory of the distal end of the manipulable portion **502** outwardly from the distal end **512b** of the catheter sheath **512** that has a “tighter” curvature than an un-modified respective trajectory that the distal end of the

67

manipulable portion **502** undergoes solely on the basis of its autonomous coiling during the advancement. In some embodiments, this situation can in turn result in a coiled advancement trajectory of the distal end of the manipulable portion **502** outwardly from the distal end **512b** of the catheter sheath **512** that is “tighter” or more closely wound than an un-modified respective trajectory that the distal end of the manipulable portion **502** undergoes solely on the basis of its autonomous bending during the advancement. A tighter, more compact or more closely wound advancement path may, in some cases, further reduce occurrences of undesired contact between the distal end of the manipulable portion **502** and the tissue surface during the advancement of the distal end of the manipulable portion **502** into the bodily cavity. It is noted that this additional bending of the structure **502a** during the take-up of the cable **513b** with the first rate imparts additional potential or spring energy in the structure. However, unlike various embodiments described in co-assigned International Patent Application No. PCT/US2012/022061 in which similar structures are bent into an arcuate or coiled configuration from a low energy configuration in which the similar structures are generally straight in form, lower amounts of potential energy are imparted onto structure **502a** by the take-up of cable **513b** since structure **502a** is being bent from a pre-formed coiled shape having a low energy state. Nonetheless, additional deflection imparted on manipulable portion **502** by cable **513b** may be limited to reduce the amount of spring-back that would occur in manipulable portion **502** should a failure in cable **513b** occur. A phantom line **502b** is representative of a portion of structure **502** in its initial or predisposed configuration (i.e., a low energy state) in FIG. 5I.

In various embodiments, further advancement of the manipulable portion **502** outwardly from the confines of first lumen **512d** further advances the distal end of manipulable portion **502** along the coiled path and coils manipulable portion **502** from a state shown in a FIG. 5I to a state as shown in FIG. 5J. In these embodiments, a second (e.g., a relatively lower) take-up rate similar to the second rate represented by the slope of portion **602c** in FIG. 6 may be employed to take up control cable **513b** since the manipulable portion **502** is being further advanced along a portion of its trajectory back generally toward the distal end **512b** of the catheter sheath **512** along a portion of the coiled path where a relatively slower take-up of the cable **513b** may be required. The slower second take-up rate may be motivated for various reasons including providing a better match for the profile of plot **600**. In some embodiments, the distal portions of the elongate members **504** in the structure **502a** may be pre-formed with a tight curvature in their initial or predisposed configuration to promote a rapid transition away from a tissue surface of the bodily cavity as the structure is advanced outwardly from the distal end **512b** of the catheter sheath **512**. Although these relatively tightly coiled distal portions of the elongate members **504** may enhance advancement of the manipulable portion **502** into the bodily cavity, they may hinder or restrict other required functions of the manipulable portion **502**. For example, fanning of the various curved portions of the coiled elongate members **504** as described later in this disclosure may be required, and various factors such as the widths of the curved portions the elongate members **504** as well as the amount of curvature along the coiled form may restrict or hinder the required fanning.

In some embodiments associated with FIG. 5J, the second take-up rate can be defined or predetermined to cause the take-up of the cable **513b** to be sufficient to additionally

68

bend the manipulable portion **502** to cause portions thereof to assume a larger radius of curvature than they would normally have from their autonomously formed shapes. The larger radius of curvature is contrasted with a phantom line **502c**, which is representative of a part of manipulable portion **502** in its initial or predisposed configuration (i.e., a low energy state). It is noted that the take-up of cable **513b** associated with FIG. 5J has imparted larger dimensions to manipulable portion **502** or structure **502a** thereof as compared with the initial or predisposed configuration of manipulable portion **502** or structure **502a** thereof. In some embodiments, this may advantageously simplify or reduce complexity for additional actions to manipulate manipulable portion **502** to cause manipulable portion **502** or structure **502a** thereof to better conform (e.g., to further expand to conform) with a tissue surface of a bodily cavity into which the manipulable portion **502** has been deployed. It is noted that a failure of cable **513b** in FIG. 5J would cause manipulable portion **502** to contract inwardly onto itself from any release of stored potential energy caused by such a failure. This can, in some embodiments, reduce occurrences of tissue damage that may be possibly associated with a failure of cable **513b**. In the sequence depicted by FIGS. 5H, 5I and 5J, an end or terminus of cable **513b** (an example of at least part of a control element) advances along a coiled path as the manipulable portion **502** is advanced outwardly from the distal end **512b** of the catheter sheath **512**.

FIG. 5L-1 shows an expanded configuration in which the manipulable portion **502** has been advanced outwardly from the confines of the first lumen **512d** sufficiently to allow potential energy from at least the respective first portions **509a** of the elongate members to be released and cause the first portions **509a** to be urged or biased to assume a lower energy state (i.e., the same or similar to their initial or predisposed configuration shown in FIG. 5A). This situation in turn causes at least the respective second portions **509b** of various ones of the elongate members **504** to autonomously fan at least in part, with respect to one another into an expanded configuration also known as a first fanned configuration **536**. In some example embodiments, as the respective third portions **509c** are advanced from the confines of catheter sheath **512**, stored potential energy is released and the respective third portions **509c** are urged or biased into a lower energy state to cause at least the respective second portions **509b** of various ones of the elongate members **504** to autonomously fan, at least in part, with respect to one another into the first fanned configuration **536**. In some example embodiments, as both the respective third portions **509c** and the respective first portions **509a** of various ones of the elongate members **504** are advanced from the confines of catheter sheath **512**, stored potential energy is released and the respective first and third portions **509a**, **509c** are urged or biased into respective lower energy states to cause at least the respective second portions **509b** of various ones of the elongate members **504** to autonomously fan at least in part, with respect to one another into the first fanned configuration **536**. In various embodiments, the manipulable portion **502** is sized too large for delivery through the first lumen **512d** at least in a direction toward the distal end portion **512b** of the catheter sheath **512** when the manipulable portion **502** is positioned in the first fanned configuration **536**. A crossing location between various elongate members **504** in the first fanned configuration **536** is positioned between the proximal and distal portions **508a** and **508b** of manipulable portion **502** in FIG. 5L-1.

In various embodiments, additional fanning mechanisms or actuators (for example, as described later in this disclo-

sure, such as with respect to FIG. 5S) may be employed to assist in the fanning of, or to promote an additional fanning of various ones of the elongate members 504 as the elongate members 504 are moved into various additional expanded configurations. Additional manipulations of manipulable portion 502 (for example, as described later in this disclosure) may be employed to further modify the expanded configuration shown in FIG. 5L-1. In various embodiments, various manipulations of manipulable portion 502 may be employed to transition the expanded configuration of the manipulable portion 502 between various particular states.

A discussion will now be made on the interplay between the metering of cable 513b and a retraction of manipulable portion 502 into the confines of first lumen 512d that occurs in some embodiments. In the state of FIG. 5J, if effort was made to retract manipulable portion 502 back into the confines of the first lumen 512d (for example by a relative movement between shaft 510 and catheter sheath 512), the tensioned cable 513b would likely impede or resist these efforts. In some cases, cable 513b would be subjected to significant forces in response to these attempts to urge the manipulable portion 502 into the first lumen 512d. In some cases, these forces may be sufficient to raise concerns about damage to or failure of the cable 513b or manipulable portion 502.

In some embodiments, the cable 513b is controlled to develop reduced tension in various portions of the cable 513b to a level or levels sufficient to reduce resistance (e.g., tension) that would impede the retraction of manipulable portion 502 into the first lumen 512d. For example, in some embodiments, cable 513b is so controlled by clutching or decoupling a take-up mechanism coupled to the cable 513b to “free-wheel” so as to allow the cable 513b to be freely pulled outwardly from the distal end 512b of the catheter sheath 512 to allow various portions of manipulable portion 502 to be retracted into the first lumen 512d with reduced levels of resistance. In some embodiments, cable 513b is played out with a metered rate to allow a portion of the cable 513b to be moved outwardly from the distal end 512b of the catheter sheath 512 in a regulated manner during the retraction of the manipulable portion 502 into the first lumen 512d. In some embodiments, cable 513b is metered to regulate reduced tension levels (e.g., slack) formed in the cable 513b. In FIG. 6, line 604 represents a particular control line metering action employed according to some embodiments. Portion 604b of line 604 is associated with a condition in which the control line (e.g., control line previously described in conjunction with FIG. 6) is played-out or metered with a third rate (e.g., represented by the slope of portion 604b of line 604) to cause a portion of the control line to have a reduced tension level (e.g., slackened). A slackened portion of the control line in some embodiments is sufficient to allow a portion of the array of elongate members protruding outwardly from the catheter sheath to autonomously bend toward (e.g., inwardly to) a lower energy position (for example, an inward location the same or similar to that represented by phantom line 502c in FIG. 5J) as the array of elongate members undergo retraction back into the catheter sheath. In FIG. 6, this part of the control line play-out occurs when the stacked elongate members have been retracted from a point approximately 200 mm along the coiled retraction path (i.e., as measured outwardly from the distal end of the catheter sheath) to a point approximately 180 mm along the coiled retraction path. At the point approximately 180 mm along the horizontal axis in FIG. 6, portion 604b of line 604 crosses plot 600 indicating that the arrayed structure is in a low energy state (for example as

represented by a retraction of manipulable portion 502 to a particular location shown in FIG. 5K). In various embodiments, further play-out of the control line in accordance with the remaining part of portion 604b of line 604 and the subsequent portion 604c of line 604 essentially maintains a portion of the arrayed structure protruding outside the catheter sheath in a low energy state as the arrayed structure is retracted back into the lumen of the catheter sheath. For example, phantom line 502b in FIG. 5I may be used to envision a position of manipulable portion 502 in a low energy state during the further play-out of the cable 513b that occurs during the retraction of the manipulable portion 502 back into first lumen 512d. It is understood that portions of the structure (e.g., structure 502a) entering the catheter sheath are brought into a higher energy state due to the shape restrictions imposed by the lumen of the catheter sheath.

During further retraction of the stacked arrangement of the elongate members into the distal end of the catheter sheath, the control line is played out or metered with a fourth rate (i.e., as represented by the slope of portion 604c of line 604) during a second part of the play-out to cause a portion of the control line to have a reduced tension level (e.g., slackened level). A slackened portion of cable 513b in some embodiments is sufficient to allow a portion of the arrangement of elongate members protruding outwardly from the catheter sheath to autonomously continue to bend toward (e.g., outwardly to) a lower energy configuration or generally maintain the lower energy configuration as the arrangement of elongate members continues to undergo retraction into the catheter sheath. In FIG. 6, this second part of the control line play-out occurs when the arrangement of elongate members has been retracted from a point of 150 mm along the retraction path to a point about 40 mm along the retraction path (i.e., again as measured outwardly from the distal end of the catheter sheath). In various embodiments, the third metering rate (e.g., as represented by the slope of portion 604b of line 604) is different than the fourth metering rate (e.g., as represented by the slope of portion 604c of line 604). For example, in FIG. 6, the third metering rate associated with the slope of portion 604b of line 604 is twice the fourth metering rate associated with the slope of portion 604c of line 604. In some embodiments, the third metering rate associated with the slope of portion 604b of line 604 is generally equal to the first metering rate associated with the slope of portion 602b of line 602. In some embodiments, the fourth metering rate associated with the slope of portion 604c of line 604 is generally equal to the second metering rate associated with the slope of portion 602c of line 602. In this regard, in some embodiments, the third metering rate may be referred to as a “2× rate”, like the first metering rate, and the fourth metering rate may be referred to as a “1× rate” like the second metering rate. Different rates may be employed in other embodiments. It is noted in various embodiments associated with FIG. 6 that a large part of line 604 remains below the data of plot 600 indicating that slack in the control line is present during or throughout the metering of the control line in conjunction with line 604.

In various embodiments, advancement of various parts of manipulable portion 502 outwardly from the confines of first lumen 512d (i.e., outwardly from the distal end 512b of catheter sheath 512) accompanies a first relative movement between the shaft 510 and catheter sheath 512 that results in a reduction or decrease in a distance between the proximal end 510a of the shaft 510 and the proximal end 512a of the catheter sheath 512 (e.g., as shown by the sequence depicted in FIGS. 5D, 5E and 5F), and also results in an increase in an amount of at least a part of the manipulable portion 502

71

extending outside the distal end of the catheter sheath **512**. In this regard, in some embodiments, the distal end of the manipulable portion **502** is located outside of the distal end **512b** of the catheter sheath **512** at a first location when a particular spatial relationship exists between the shaft **510** and the catheter sheath **512** during the first relative movement. See, e.g., the non-phantom lined first location of the distal end of the manipulable portion **502** in FIG. **5I**. A reduction in a distance between the proximal end **510a** of shaft **510** and the proximal end **512a** of catheter sheath **512** may correspond to a reduction in a distance between a location on shaft **510** and a location on catheter sheath **512** during the first relative movement. In various embodiments, this reduction in distance may be accomplished by (a) a forward advancement of shaft **510** (e.g., away from housing **520** in FIG. **5A**), (b) a rearward retraction of catheter sheath **512** (e.g., toward housing **520**), or both (a) and (b).

In various embodiments, retraction of various parts of manipulable portion **502** inwardly into the confines of first lumen **512d** (i.e., inwardly into the distal end **512b** of catheter sheath **512**) accompanies a second relative movement between the shaft **510** and catheter sheath **512** that results in an increase in a distance between the proximal end **510a** of the shaft **510** and the proximal end **512a** of the catheter sheath **512** (i.e., for example, as may occur in a sequence reverse to the sequence depicted in FIGS. **5D**, **5E** and **5F**), and also results in a decrease in an amount of at least a part of the manipulable portion **502** extending outside the distal end of the catheter sheath **512**. In this regard, in some embodiments, the distal end of the manipulable portion **502** is located outside of the distal end **512b** of the catheter sheath **512** at a second location (different than, e.g., the non-phantom lined first location of the distal end of the manipulable portion **502** in FIG. **5I**) when the same particular spatial relationship exists (as compared to advancement of various parts of manipulable portion **502** outwardly from the confines of first lumen **512d**, discussed above) between the shaft **510** and the catheter sheath **512** during the second relative movement, the particular spatial relationship being a spatial relationship between a third location on the shaft **510** and a fourth location on the catheter sheath **512**. See, e.g., the phantom lined second location of the distal end of the manipulable portion **502** in FIG. **5I**. An increase in a distance between the proximal end **510a** of shaft **510** and the proximal end **512a** of catheter sheath **512** may correspond to an increase in a distance between a (third) location on shaft **510** and a (fourth) location on catheter sheath **512** during the second relative movement. In various embodiments, this may be accomplished by (a) a rearward retraction of shaft **510** (e.g., in a direction toward the housing **520** in FIG. **5A**), (b) a forward advancement of catheter sheath **512b** (e.g., in a direction away from the housing **520**), or both (a) and (b).

In some embodiments, a control system or actuator system (e.g., as described herein) that is operatively or physically coupled to the manipulable portion **502** varies a size, a shape, or both, of the manipulable portion **502**. In some embodiments, the control system or actuator system may respond to or be controlled by the first relative movement by causing at least one actuator to vary a size, a shape, or both, of at least part of the manipulable portion **502** extending outside (or located outside) the distal end **512b** of catheter sheath **512** to, at least in part, cause the distal end of the manipulable portion **502** to move along a first trajectory during the first relative movement (for example as described above with respect to line **602** in FIG. **6**). As discussed above, the first relative movement may be a relative movement between the catheter sheath **512** and a part of the shaft

72

510 when a distance between a location on the part of the shaft **510** and a location on the catheter sheath **512** decreases (e.g., as shown by the sequence depicted in FIGS. **5D**, **5E** and **5F**)

The control system or actuator system may additionally respond to or be controlled by the second relative movement by varying a size, a shape, or both of at least the part of the manipulable portion **502** extending outside (or located outside) the distal end **512b** of catheter sheath **512** to, at least in part, cause the distal end of the manipulable portion **502** to move along a second trajectory during the second relative movement (for example as described above with respect to line **604** in FIG. **6**). In some of these embodiments, the first trajectory and the second trajectory are different trajectories. As discussed above, the second relative movement may be a relative movement between the catheter sheath **512** and a part of the shaft **510** when a distance between a location on the part of the shaft **510** and a location on the catheter sheath **512** increases (e.g., as may occur in a sequence reverse to the sequence depicted in FIGS. **5D**, **5E** and **5F**). As used in this disclosure, the word trajectory means a path described by an object moving in space (e.g., a gaseous or fluidic space) under the influence of various forces. It is understood that the word trajectory refers to the path of movement and not the particular direction of travel along the path of movement. That is, travel along a particular trajectory from either direction is considered to be travel along the same trajectory in either case.

With respect to FIGS. **5H**, **5I** and **5J**, a distal end **505a** of the manipulable portion **502** moves along a first trajectory under the influence of a control element (e.g., the metered cable **513b**), according to some embodiments. The control element (e.g., metered cable **513b**), in some embodiments, is operatively or physically coupled to a control system or actuator system to, at least in part, cause the distal end of the manipulable portion to move along the first trajectory. In this regard, in some embodiments, the first trajectory is a modified trajectory following a respective path along which the distal end of the manipulable portion **502** moves during the first relative movement as compared to a respective trajectory along which the distal end of the manipulable portion **502** would move during the first relative movement absent the control element (e.g., the metered cable **513b**). For example, in some embodiments, the first trajectory is modified from a trajectory that the distal end **505a** of the manipulable portion **502** would follow solely from the autonomous coiling of the manipulable portion during the advancement of the manipulable portion **502** outwardly from the distal end **512b** of the catheter sheath **512**.

In some embodiments, (a) the distal end of the manipulable portion **502** follows a coiled path during the first relative movement, (b) the distal end of the manipulable portion **502** follows a coiled path during the second relative movement, or both (a) and (b). In some embodiments, the control system or actuator system responds to or is controlled by, the first relative movement by varying a radius of curvature of a surface of at least part of the manipulable portion **502** extending outside the distal end **512b** of catheter sheath **512** to decrease during the first relative movement (for example, as shown in FIG. **5I**) and then subsequently increase (for example as shown in FIG. **5J**) during the first relative movement.

In various embodiments, the manipulable portion **502** is selectively moveable between a delivery configuration in which the manipulable portion **502** is sized, shaped, or both sized and shaped to be delivered through the first lumen **512d** of catheter sheath **512** and an expanded configuration

in which the manipulable portion **502** is sized, shaped or both sized and shaped too large for delivery through the first lumen **512d**. In some of these various embodiments, an actuator system (e.g., one or more of the components of at least FIG. **5R**, **5S**, **5W**, **7**, **8**, or **10**) is physically or operatively coupled to at least a control element (e.g., cable **513b**), and may be controlled by a control system (e.g., one or more components of at least control system **322** or control system **545**) to transition the manipulable portion **502**, at least in part, toward or to the expanded configuration as the manipulable portion is advanced out of the distal end **512b** of the catheter sheath **512**, and to transition, at least in part, the manipulable portion **502** toward or to the delivery configuration as the manipulable portion is retracted into the distal end **512b** of the catheter sheath **512**. In some embodiments, the control system or actuator system is operatively or physically coupled to the control element (e.g., cable **513b**) to cause, when a particular amount of the manipulable portion **502** is located outside of the distal end **512b** of the catheter sheath **512** during the transition toward or to the expanded configuration, at least a portion of the control element (e.g., cable **513b**) to have a first amount of length located outside the distal end **512b** of the catheter sheath **512** (for example, cable **513b** in FIG. **5I** is shown with a first amount of length during the outward advancement of manipulable portion **502**).

The control system or actuator system may be operatively or physically coupled to the control element (e.g., cable **513b**) to cause, when the same particular amount of the manipulable portion **502** is located outside of the distal end **512b** of the catheter sheath **512** during the transition toward or to the delivery configuration, at least the portion of control element (e.g., cable **513b**) to have a second amount of length located outside of the distal end **512b** of the catheter sheath **512**, the second amount of length being different than the first amount of length. For example, although FIG. **5I** is associated with the outward advancement of manipulable portion **502** from catheter sheath **512**, phantom line **502b** can be envisioned to reflect a same particular amount (e.g., a length or other dimension) of the manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512** to the distal end of the manipulable portion **502** during a retraction of the manipulable portion **502** as compared to advancement thereof. Cable **513b** is represented as cable **513b(ret)** (i.e., shown in broken lines) for the case of retraction. When the same particular amount of the manipulable portion **502** is located outside the distal end **512b** of catheter sheath **512** during the retraction of manipulable portion **502** as compared with the advancement of manipulable portion **502**, the amount of length of cable **513b**, **513b(ret)** located outside of the distal end **512b** of catheter sheath **512** is greater during the retraction of manipulable portion **502** than during the advancement of manipulable portion **502** (e.g., length of cable **513b(ret)** outside the distal end **512b** is greater than length of cable **513b** outside the distal end **512b**).

In some embodiments, the particular amount of the manipulable portion located outside the distal end **512b** of the catheter sheath **512** is a particular size of the manipulable portion between the distal end **512b** of the catheter sheath **512** and the distal end of the manipulable portion **502**. In some embodiments, the particular amount of the manipulable portion located outside the distal end **512b** of the catheter sheath **512** is a particular length of the manipulable portion **502** extending from the distal end **512b** of the catheter sheath **512** to the distal end of the manipulable portion **502**. In some embodiments, the particular amount of

the manipulable portion located outside the distal end **512b** of the catheter sheath **512** is a particular length of the manipulable portion **502** extending along a surface of the manipulable portion **502** from the distal end **512b** of the catheter sheath **512** to the distal end of the manipulable portion **502**.

In some embodiments, the control system or actuator system is physically or operatively coupled to the control element (e.g., cable **513b**) to cause, when a particular relative positioning (e.g., a relative longitudinal positioning) exists between the catheter sheath **512** and the shaft **510** received in the first lumen **512d** of the catheter sheath **512** during the transition toward or to the expanded configuration, at least part of the control element to have a first amount of length located outside of the distal end **512b** of the catheter sheath **512**. The control system or actuator system may be physically or operatively coupled to the control element (e.g., cable **513b**) to cause, when the same particular relative positioning exists between the catheter sheath **512** and the shaft **510** received in the first lumen **512d** during the transition toward or to the delivery configuration, at least part of the control element (e.g., cable **513b**) to have a second amount of length located outside of the distal end **512b** of the catheter sheath **512**, the second amount of length being different than the first amount of length. In some embodiments, the control system or actuator system is physically or operatively coupled to the control element (e.g., cable **513b**) to cause, when the particular relative positioning (e.g., a relative longitudinal positioning) exists between the catheter sheath **512** and the shaft **510** received in the first lumen **512d** of the catheter sheath **512** during the transition toward or to the expanded configuration, the control element (e.g., cable **513b**) to have a third amount of length located outside of end **513a-1** (i.e., shown in FIG. **5C**) of sleeve **513a**. In addition, the control system or actuator system may be physically or operatively coupled to the control element (e.g., cable **513b**) to cause, when the same particular relative positioning exists between the catheter sheath **512** and the shaft **510** received in the first lumen **512d** during the transition toward or to the delivery configuration, the control element to have a fourth amount of length located outside of the end **513a-1** of sleeve **513a**, the fourth amount of length being different than the third amount of length. In some embodiments, cable **513b** and sleeve **513a** form part of a Bowden cable (e.g., third Bowden cable **555**, called out in FIG. **7**).

An actuator system (e.g., part or all of system **545**, in some embodiments), which may be controlled at least in part by a control system (e.g., one or more components of control system **322**, control system **545**, or both control system **322** and control system **545** described in this disclosure), may employ one or more various actuators to manipulate or control various portions of a control element (e.g., control element **513**) in accordance with various embodiments. For example, in some embodiments the use of projection **528** and receiver **529** may be employed to control a portion of control element **513**. For instance, existence of a particular state (e.g., location, amount of tension, or both) of the control of control element **513** may be based, at least in part, on a particular amount of the length **528a** received in receiver **529**. It is noted that, in some embodiments, a particular aspect of the control of control element **513** based on a particular positioning between catheter sheath **512** and shaft **510** in the first lumen **512d** of catheter sheath **512** may be analogous to a particular aspect of the control of control

75

element **513** that is based, at least in part, on a particular amount of the length **528a** of projection **528** received in receiver **529**.

In some embodiments, the use of projection **528** and receiver **529** may be employed to meter cable **513b** in a manner that is the same or similar to that described with respect to FIG. 6. In some embodiments, an actuator system (e.g., one or more of the components of at least FIG. 7 or others, in some embodiments) is operatively or physically coupled to the manipulable portion **502** (e.g., via each of at least one of a plurality of Bowden cables, for example, first Bowden cable **552** (an example of at least part of a control element) or cable **513b** thereof) to transmit force to the manipulable portion. This operative coupling between the actuator system and the manipulable portion **502** may be configured to meter, e.g., control cable **513b** to vary an amount of the cable **513b** that extends outwardly (or is located outwardly) from the distal end **512b** of catheter sheath **512** when part of shaft **510** is received in the first lumen **512d** of catheter sheath **512** and, e.g., during a change in a size, a shape, or both, of the manipulable portion **502**. In some embodiments, the actuator system may be configured to respond to, or be controlled by, varying amounts of the length **528a** of projection **528** being within the receiver **529** by varying a rate in which the cable **513b** is metered. In some embodiments, the actuator system responds to or is controlled by a rate of change in an amount of the length **528a** of the projection **528** being within the receiver **529** by varying a rate in which the cable **513b** is metered.

Turning now to FIGS. 5R-1 and 5R-2, respective top and bottom perspective views are illustrated of a part of catheter system **500** with various external portions of housing **520** removed for viewing of various internal mechanisms and actuators contained, at least in part, in housing **520**. In each of FIGS. 5R-1 and 5R-2, at least part of projection **528** is shown received in receiver **529**, while a portion of shaft **510** is received in first lumen **512d** (not called out in FIG. 5R-2). For clarity, various portions of catheter system **500** (e.g., manipulable portion **502**) are not shown in FIGS. 5R-1 and 5R-2. As best seen in FIG. 5R-1, a first actuator set **540**, which may comprise some or all of an actuator system, includes a first particular actuator **540a** and a second particular actuator **540b**, the operation of each of which is described later in this disclosure. In this regard, the first actuator set **540** is located at least proximate the proximal end **510a** of the shaft **510**, according to some embodiments. As best seen in FIG. 5R-1, cable **513b** (e.g., a portion of control element **513**) extends along a particular path toward or to the second particular actuator **540b**. In some embodiments, each actuator in the first actuator set **540** is operatively coupled to the manipulable portion by at least one respective flexible control element (e.g., at least the control cable **513b**) arranged to selectively transmit force provided by the respective actuator in at least the first actuator set **540** to the manipulable portion **502**.

Each of the actuators in the first actuator set **540** may be independently, separately, or selectively moveable from the other actuators in the first actuator set **540** from a respective first activation position toward or to a respective second activation position to vary a size, shape, or both a size and a shape of a deployed or expanded configuration of the manipulable portion **502** into a particular state. Each of the actuators in the first actuator set **540** may include various passive and active components suitable for causing force to be transmitted to manipulable portion **502** to change a size or shape thereof according to various embodiments. Different types of actuators may be employed in various embodi-

76

ments. By way of non-limiting example, various ones of the first actuator set **540** can include a rotary actuator, a portion of which is rotatable from a first activation position toward or to a second activation position to cause a size, shape, or both a size and a shape of manipulable portion or structure **502a** thereof to be varied.

In some embodiments, a third particular actuator **572** (described in detail later in this disclosure) is employed. In some embodiments, actuator **572** may be independently, separately, or selectively moveable from the other actuators (e.g., actuators in the first actuator set **540**) from a respective first activation position toward or to a respective second activation position to vary a size, shape, or both a size and a shape of a deployed or expanded configuration of the manipulable portion **502** into a particular state. In some embodiments, actuator **572** is a particular actuator in a second actuator set **541**, in which actuator **572** is moveable between two activation positions to cause one or more actuators (or sometimes two or more actuators in some embodiments) in the first actuator set **540** that are positioned in their respective second activation positions to move away from their respective activation positions as described later in this disclosure. The second actuator set **541** may comprise some or all of an actuator system. In some embodiments, the second actuator set **541** is located at least proximate the proximal end **510a** of the shaft **510**.

In FIGS. 5R-1 and 5R-2, each of actuators **540a**, **540b**, and **572** is a linear actuator, a portion of each translatable from a respective first activation position toward or to a respective second activation position to cause a size, shape, or both a size and a shape of manipulable portion **502** or structure **502a** thereof to be varied. In FIGS. 5R-1 and 5R-2, each of actuators **540a**, **540b**, **572** is a linear actuator, a portion of each translatable from a respective first activation position toward or to a respective second activation position (for example, as described later in this disclosure) to cause a size, shape, or both a size and a shape of an expanded configuration of the manipulable portion **502** or structure **502a** thereof to be varied into a particular state. In FIGS. 5R-1 and 5R-2, a portion of each of actuators **540a** and **540b** is guided by a respective one of guides **542a**, **542b** of guide system **542**. In FIG. 5R-1, a portion of actuator **572** is guided by a guide **542e**. In various embodiments, guide system **542** is configured to capture various portions (e.g., slider portions) of each of actuators **540a**, **540b** and **572** while allowing the portions of each of actuators **540a**, **540b**, and **572** to slide along a respective one of guides **542a**, **542b**, **542e**. In some embodiments, guide system **542** is provided at least in part by an extrusion (e.g., an aluminum extrusion) while various portions of each of actuators **540a**, **540b**, and **572** can include a combination of metallic and non-metallic components. In various embodiments, each of various ones of the guides of guide system **542** includes a guide channel. In various embodiments, each of various ones of the guides of guide system **542** includes a guide rail.

In various embodiments illustrated in FIGS. 5R-1 and 5R-2, each of various ones of the guides (e.g., guides **542a**, **542b**) includes a channel-like member configured to at least partially enclose respective ones of at least some of the actuators in the first and second actuator sets **540**, **541**. In various embodiments, each of actuators **542a** and **542b** includes a respective one of handles **543a** and **543b**, each of the handles **543a**, **543b** manipulable by a user (e.g., a health care provider or technician) to move the respective one of actuators **540a**, **540b** at least toward or away from its respective second activation position. In various embodiments, each of the handles **543a**, **543b** is engageable to move

the respective one of actuators **540a**, **540b** toward or away from (a) its respective first activation position, (b) its respective second activation position, or both (a) and (b). In various embodiments, each of one or more of actuators **540a**, **540b** is selectively lockable to maintain one or more desired positions (e.g., the second activation position) along respective ones of the guides **542a**, **542b**. For example, in some embodiments, each or one or more of handles **543a**, **543b** is rotatable (for example, in a clockwise direction) to lock a respective one of actuators **540a**, **540b** so as to maintain a desired positioning along a respective one of guides **542a**, **542b**. In some embodiments, each of one or more of handles **543a**, **543b** is rotatable (for example, in a counter-clockwise direction) to unlock a respective one of actuators **540a**, **540b** so as to allow the respective one of actuators **540a**, **540b** to move away from a particular positioning along a respective one of guides **542a**, **542b**. The locking of a particular actuator of the first set actuators **540** may be accomplished by various mechanisms that can cause the particular actuator to grip or otherwise become secured to a guide **542**.

In some embodiments, various ones of handles **543a**, **543b** may be physically or operatively coupled to one or more cams that can be selectively brought into and out of frictional engagement with a guide of the guide system **542**. For example, FIGS. **10A** and **10B** show respective perspective views of a locking device **1010** employed by a slider **1000** which may function in a similar or same manner to one or both of actuators **540a**, **540b** according to some embodiments. In this regard, in some embodiments, each respective actuator in the first actuator set **540** may include a respective locking device like that shown in FIG. **10**.

In some embodiments, the locking device **1010** is selectively moveable between or operable in an unlocked configuration (e.g., FIGS. **10A** and **10C**) and a locked configuration (e.g., FIGS. **10B** and **10D**). In embodiments where the locking device **1010** is part of an actuator (e.g., each of one or more actuators in the first set of actuators **540**), the unlocked configuration permits or allows the actuator to move (e.g., at least in a direction toward or away from a respective activation position). In embodiments where the locking device **1010** is part of an actuator (e.g., each of one or more actuators in the first set of actuators **540**), the locked configuration restricts or prevents the actuator from moving (e.g., at least in the direction toward or away from a respective activation position).

In FIG. **10A**, locking device **1010** is in an unlocked configuration which allows slider **1000** to move with respect to a guide element (not shown for clarity but similar to, or the same as one or both of guides **542a**, **542b** in some embodiments), while in FIG. **10B**, locking device **1010** is in a locked configuration which restricts slider **1000** from moving with respect to the guide element. Detailed perspective views of locking device **1010** are provided in FIG. **10C** (i.e., unlocked configuration) and FIG. **10D** (i.e., locked configuration). Various parts of slider **1000** are not shown in FIGS. **10C** and **10D** to better show parts of locking device **1010** not visible in FIGS. **10A** and **10B**. In some embodiments, locking device **1010** employs a plurality of locking cams **1015** (i.e., four in this illustrated embodiment) that may be selectively moved between the unlocked configuration and the locked configuration. In some embodiments, the locking cams **1015** are moved between the unlocked and the locked configuration by rotation of handle **1020** (which may correspond to handle **543a**, **543b**, or each of **543a** and **543b** in some embodiments). For example, in some embodiments, handle **1020** is physically coupled to a drive cam

1025 of locking device **1010** in a manner suitable for rotating the drive cam **1025** in each of a clockwise or counter clockwise direction. In some embodiments, drive cam **1025** is engageable with one or more (two in this illustrated embodiment) cam followers **1030**. Each of the cam followers **1030** may include a drive pin **1035** received in a respective channel **1040** provided in each of the locking cams **1015**. Rotation of handle **1020** in a manner that rotates drive cam **1025** such that it forces the cam followers **1030** relatively further apart from one another causes the locking device **1010** to move from the unlocked configuration (e.g., FIGS. **10A**, **10C**) toward or to the locked configuration (e.g., FIGS. **10B**, **10D**) by causing the drive pins **1035** to rotate the locking cams **1015** (i.e., about pivots **1045**) outwardly into frictional engagement with the guide element (not shown for clarity but similar to, or the same as one or both of guides **542a**, **542b** in some embodiments). Rotation of the drive cam **1025** in an opposite direction may be employed to restore the locking device **1010** back to its unlocked configuration. In some embodiments, biasing members **1050** employ a biasing action that biases the locking device **1010** toward or to the unlocked configuration. Other locking/unlocking mechanisms may be employed in other embodiments.

Returning to FIGS. **5R-1** and **5R-2**, actuator **572** includes cover **520a** in various embodiments. For example, in FIGS. **5R-1** and **5R-2** cover **520a** is operatively coupled to a first fanning slider **572a** that makes up at least part of actuator **572** and which is guided by guide system **542**. In this illustrated embodiment, the cover **520a** is physically coupled to first fanning slider **572a** via fasteners **520b** and biasing element **520c**. Biasing element **520c** may include a compression spring in some embodiments. In some embodiments, cover **520a** forms a handle of actuator **572**. Other operations or functions associated with cover **520a** are described later in this disclosure. The interaction of cover **520a** with respect to actuator **572** is shown in exploded view in each of FIGS. **5R-1** and **5R-2** for clarity of illustration.

In various embodiments, catheter system **500** includes a control system **545** (which also may be referred to as an actuator system in some embodiments) comprising a set of devices or a device system that manages, controls, directs, or regulates the behavior of other device(s) or sub-system(s) that make up system **500**. For example, control system **545** can, in some embodiments, control or include a transition actuator (e.g., actuator **540a**, **540b**, **546**, **572**, some other actuator or actuator set, or a portion of at least one of these actuators) physically or operatively coupled to the manipulable portion **502** to transition or modulate manipulable portion **502** or structure **502a** thereof at least partially between various states or configurations (e.g., between a delivery configuration and an expanded or deployed configuration, or vice versa). In some embodiments, control system **545** is configured to control or include a modulation actuator (e.g., an actuator in FIG. **7**, some other actuator or actuator set, or a portion of at least one of these actuators) physically or operatively coupled to the manipulable portion **502** (e.g., via at least the elongated control element **513**) to modulate at least a size, a shape, or both a size and a shape of manipulable portion **502**, for example, at least in a state where at least a part of the manipulable portion **502** and a part of the control element **513** extend outside the distal end of the catheter sheath **512** (e.g., FIG. **5C**). In some embodiments, control system **545** can control or include a control element manipulation actuator (e.g., an actuator in FIG. **5S** or **7**, some other actuator or actuator set, or a portion of at least one of these actuators) to manipulate various control

elements (e.g., control element **513**) in system **500**. In some embodiments, various ones of the transition, modulation, and control element manipulation actuators may be the same or separate devices or may be combined into a single device or system. For example, one of the actuators in FIG. **5S** or **7** may be deemed a transition actuator, another one of these actuators may be deemed a modulation actuator, and yet another one of these actuators may be deemed a control element manipulation actuator. Or, in some embodiments, some or all of the transition actuator, modulation actuator, and control element manipulation actuator may be the same actuator. The points made in this discussion also apply to other actuators described herein. In various embodiments, various actuators (e.g., modulation, transition, and control element manipulation actuators) controlled by control system **545** may form part of control system **545** or may be distinct from control system **545**. In some embodiments, the control system **545** may include one or more components of system **100** or control system **322**, such as controller **324**, that control one or more of the actuators described in this paragraph or otherwise herein.

Control system (which may also be referred to as an actuator system) **545** may trigger, be triggered, or cause an operation of a series of mechanical actuators in the correct sequence to perform a task associated with catheter system **500**. Control system **545** may, in some embodiments, include a feedback system responsive to various inputs (e.g., user actions, machine action, or a combination of both) to initiate a particular function or transition between particular functions of system **500**. In some embodiments, control system **545** is provided at least in part by at least one data processor, for example, as provided by one or more components of system **100** or control system **322**, such as controller **324**, and as such may be responsive to or controlled by various transducer data, machine data, or data input by a user. In various embodiments, control system **545** includes or takes the form of a mechanical system that includes a receiving mechanism configured to receive input force or input movement and a conversion mechanism that converts the input force or input movement to achieve a particular application of output force or output movement. In some of these various embodiments, the mechanical system may include various sensors, force limiters, or movement limiters that compare the output to a desired value and then directs the input or the conversion of the input. In some embodiments, control system **545** is entirely provided by a mechanical system. In some embodiments, input force or input movement is provided manually. Manual application of force or movement may be preferred for some medical device systems to avoid undesired outcomes that may accompany a misapplication of power-based (e.g., electrical, hydraulic or pneumatic) force or movement. Some example operations associated with control system **545** are schematically represented, according to some embodiments, in FIGS. **7A** and **7B**, which are described in more detail later in this disclosure.

In various embodiments, control system (which also may be referred to as an actuator system in some embodiments) **545** is responsive to or is controlled by relative movement between shaft **510** and catheter sheath **512** (e.g., at least when a portion of shaft **510** is received in the first lumen **512d** of catheter sheath **512**) to (a) modulate or control a particular configuration or state of manipulable portion **502** (e.g., by varying a force applied to the manipulable portion **502**), (b) control a transition between various particular configurations or states of manipulable portion **502**, (c) manipulate a control element (e.g., control element **513**) or

some particular combination of some or all of (a), (b), and (c). In some embodiments, control system **545** is responsive to or controlled by varying amounts of the length **528a** of projection **528** being received within receiver **529** to (a) modulate or control a particular configuration or state of manipulable portion **502** (e.g., by varying a force applied to the manipulable portion **502**), (b) control a transition between various particular configurations or states of manipulable portion **502**, (c) manipulate a control element (e.g., control element **513**), or some particular combination of some or all of (a), (b), and (c). In this regard, in some embodiments, the control system **545** responds to or is controlled by movement of the internal receiving mechanism **546** within the receiver **529** caused by a change in an amount of the length of the projection **528** within the receiver **529** by varying the force transmitted to the manipulable portion **502**. In some embodiments, the control system **545** responds to or is controlled by a rate of change in an amount of the length of the projection **528** within the receiver **529** by varying a rate at which a control cable (e.g., cable **513b**) is metered, e.g., as described with respect to FIG. **6** in this disclosure.

In some embodiments, at least a portion of at least one actuator (e.g., **546**, described later in this disclosure, which may include a modulation actuator) is moveable in each of a first direction and a second direction different than the first direction. In some embodiments, the control system **545** may be configured to cause at least the portion of the actuator (e.g., modulation actuator) to move in the first direction to cause or accompany an increase in an amount of manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512** and may be configured to cause at least the portion of the actuator (e.g., modulation actuator) to move in the second direction to cause or accompany a decrease in an amount of manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512**. In other words, at least the actuator (e.g., modulation actuator) may be operable to cause or accompany an increase or decrease in the amount of manipulable portion **502** extending outwardly from the distal end **512b** of catheter sheath **512**, depending upon when at least a portion of the actuator moves in the first direction or second direction, respectively.

In some embodiments associated with FIGS. **5R-1** and **5R-2**, the receiver **529** includes an internal receiving mechanism **546** (which may be an example of an actuator or a particular actuator) configured to engage with a part of projection **528** received in receiver **529**. In some embodiments, the internal receiving mechanism **546** is sized to matingly receive at least a portion of the projection **528**. As best seen in FIG. **5R-2**, the internal receiving mechanism **546** includes a coupler portion **546a** (also referred to as coupler **546a**) and a slider portion **546b** (also referred to as receiver slider **546b**) physically coupled to the coupler **546a**. Receiver slider **546b** is configured to move along guide **542c** of guide system **542**. In various embodiments, coupler **546a** captively or otherwise physically couples the internal receiving mechanism **546** to at least the portion of the projection **528** matingly received in the internal receiving mechanism **546**. The captive coupling allows at least the coupler **546a** of internal receiving mechanism **546** to move along guide **542c** during each of a first relative movement between projection **528** and receiver **529** that increases the amount of length **528a** of projection **528** within receiver **529**, and a second relative movement between projection **528** and receiver **529** that decreases the amount of length **528a** of projection **528** within receiver **529**. In various embodiments,

81

coupler **546a** includes a set of gripper arms **546c** configured to engage or otherwise physically couple with a recess **528c** of first projection **528** as best shown in FIG. **5R-3** which is a detailed view of part of FIG. **5R-2**. In some of these various embodiments, the gripper arms **546c** are biased to move apart (for example by means of a flexure) to disengage from recess **528c** when the coupler **546a** is positioned at a particular location along guide **542c** (e.g., at location **535**) where the gripper arms **546c** are not constrained by a channel associated with guide system **542**. This arrangement advantageously allows at least a portion of the projection **528** to self-couple (e.g., physically couple) to the coupler **546a** (and internal receiving mechanism **546**) when a first relative positioning between projection **528** and receiver **529** positions the gripper arms **546c** within a confining structure of guide **542c**, the positioning of the gripper arms **546c** in the confining structure causing the gripper arms **546c** to move together in a pinching or gripping manner that securely couples the gripper arms **546c** to projection **528**. Additionally, this arrangement advantageously allows at least a portion of the projection **528** to self-decouple (e.g., physically de-couple) from coupler **546a** (and internal receiving mechanism **546**) when a second relative positioning (different than the first relative positioning) between projection **528** and receiver **529** positions the gripper arms **546c** at a location (e.g., location **535**) where the gripper arms **546c** are not confined but are allowed to move or flex apart to release the projection **528** from the gripper arms **546c**, thereby allowing the shaft **510** and catheter sheath **512** to be pulled apart and become fully separated, if desired.

FIGS. **7A** and **7B** schematically show an operation of at least one actuator of a control system (which may also be referred to as an actuator system in some embodiments) **545** associated with housing **520** at two successive points in time. In various embodiments, operation of various actuators and control elements associated with FIGS. **7A** and **7B** may be employed during a change in a size, a shape, or both a size and a shape of manipulable portion **502** (not shown in FIGS. **7A** and **7B**). In various embodiments, operation of various actuators and control elements associated with FIGS. **7A** and **7B** may be employed to cause, at least in part, a change in a size, a shape, or both a size and a shape of manipulable portion **502** (for example as depicted in the sequence shown in FIGS. **5H**, **5I** and **5J**). In FIGS. **7A** and **7B**, schematic representations are employed for ease of discussion. Additionally, for the ease of discussion, the movement proximally or distally of various elements in FIG. **7A**, **7B** as discussed herein is made in accordance with the “◀DISTAL” and “PROXIMAL▶” indicators provided at the bottom of each of the FIGS. **7A** and **7B**. In this regard, in some embodiments, each of the control system **545** and at least one actuator or modulation actuator (e.g., **540a**, **540b**, **546**, **572**, some other actuator or actuator set, or a portion of at least one of these actuators) thereof are located, at least in part, at respective locations at least proximate the proximal end of the shaft **510**.

In some embodiments, the coiling/uncoiling motion during deployment/retraction of the manipulable portion **502** (e.g., FIGS. **5H**, **5I**, and **5J**) is caused and controlled, at least in part, by activation or movement of a second particular actuator **540b** and an internal receiving mechanism **546** with respect to a first particular actuator **540a**, which may act as an anchor in some configurations. In some embodiments, the coiling/uncoiling motion during deployment/retraction involves a metering of a portion of the control element **513** (e.g., a cable **513b**) with different rates under the control of a master slider **556a**, a sleeve slider **556b**, and the second

82

particular actuator **540b**. In some embodiments, movement of the first particular actuator **540a** causes or controls flattening of the manipulable portion **502** (e.g., FIGS. **5N** and **5O**). In some embodiments, clam shelling of the manipulable portion (e.g., FIGS. **5P** and **5Q**) may be caused and controlled by activation or action of the second particular actuator **540b**.

With this context in mind, a portion of control element **513** may be operatively coupled to second particular actuator **540b** to at least in part control coiling/uncoiling of the manipulable portion **502** during deployment/retraction. In some embodiments, the second particular actuator **540b** includes various portions including a first slider portion **548a** (also referred to in some embodiments as sleeve slider **548a**) configured to slide along guide **542b**, and a second slider portion **548b** (also referred to in some embodiments as slave slider **548b**) configured to slide within or with respect to, sleeve slider **548a**. In some of these various embodiments, a portion of sleeve **513a** proximate a proximal end **513a-2** of sleeve **513a** (i.e., an end of sleeve **513a** located relatively closer to the proximal end **510a** of shaft **510** than the distal end **510b** of shaft **510**) is physically coupled (or, in some embodiments, fixedly coupled) to sleeve slider **548a**. In this regard, axial or longitudinal movement of sleeve slider **548a** along guide **542b** can also cause longitudinal or axial movement of a portion of sleeve **513a** in second lumen **511** within shaft **510**. A particular location of sleeve slider **548a** along guide **542b** can be maintained by operating handle **543b** to operate an associated lock as described herein.

As shown in FIGS. **7A** and **7B**, a first part **513b-1** of cable **513b** extends outwardly from a first end **552a-1** of sleeve **552a** at least across a region of space **550**, the region of space **550** extending between first end **552a-1** and end **513a-2** of sleeve **513a**. Cable **513b** further extends through a lumen of a sleeve **552a** and is physically or operatively coupled to first particular actuator **540a**. In particular, a second part **513b-2** of cable **513b** extends outwardly from a second end **552a-2** of sleeve **552a** along a path that extends to first particular actuator **540a**. In FIGS. **7A** and **7B**, sleeve **552a** is physically coupled (or, in some embodiments, fixedly coupled) to slave slider **548b** to accompany or move in tandem with slave slider **548b**. In some embodiments, sleeve **552a** and cable **513b** form part of a Bowden cable (e.g., first Bowden cable **552**). In various embodiments, the first part **513b-1** of cable **513b** includes at least the portion **514** of cable **513b** (not shown in FIGS. **7A** and **7B**, but shown at least in FIGS. **5H**, **5I** and **5J**). In some embodiments, the part **513b-1** of cable **513b** is physically coupled to manipulable portion **502** to, at least in part change the size, shape, or both, of the manipulable portion **502**. A size of the region of space **550** varies when the slave slider **548b** moves relative to the sleeve slider **548a**. When the slave slider **548b** is distally positioned as shown in FIG. **7A**, the region of space **550** has a relatively smaller size than when the slave slider **548b** is proximally positioned (e.g., as shown in FIG. **7B**). The varying size of region of space **550** will result in different distances between the end **513a-2** of the sleeve **513a** and first end **552a-1** of sleeve **552a** in various embodiments. It is noted that various levels of tension on the cable **513b** can lead to shortening of a distance between the end **513a-2** of the sleeve **513a** and first end **552a-1** of sleeve **552a**. In some embodiments, tension on the cable **513b** may urge the slave slider **548b** to move distally.

In various embodiments, a first part **554b-1** of a second cable **554** extends outwardly from the first end **554a-1** of a second sleeve **554a**. In some embodiments, the second cable

83

554b is located at least in part of a lumen of second sleeve 554a, and second cable 554b and second sleeve 554a form part of a Bowden cable (e.g., second Bowden cable 554). In various embodiments, the first part 554b-1 of second cable 554b is physically coupled (or, in some embodiments, fixedly coupled) to the slave slider 548b. In some of these various embodiments, second cable 554b is operable to allow for a movement of the slave slider 548b in at least one of the proximal and distal directions. In some embodiments associated with FIGS. 7A and 7B, second sleeve 554a is physically coupled (or, in some embodiments, fixedly coupled) to sleeve slider 548a. It is noted in various embodiments that when the sleeve slider 548a is moved along guide 542b, sleeve 513a, slave slider 548b, and at least the respective first ends 552a-1, 554a-1 of sleeve 552a and second sleeve 554a also move with sleeve slider 548a. It is also noted in some embodiments that little or no relative movement between the sleeve 513a and the cable 513b occurs due to an adjustment in a positioning of the sleeve slider 548a, for example, as described later in this disclosure.

In various embodiments, the first part 554b-1 of cable 554b of the second Bowden cable 554 is physically or operatively coupled to the first Bowden cable 552 to cause at least the first end 552a-1 of the respective sleeve 552a of the first Bowden cable 552 to translate in response to, or during, at least part of a varying, caused by at least one actuator (e.g., 540b, 546, some other actuator or actuator set, or a portion of at least one of these actuators), of the amount of length of the first part 554b-1 of the cable 554b of the second Bowden cable 554 that extends outwardly from the first end 554a-1 of the respective sleeve 554a of the second Bowden cable 554. In some embodiments, the control (or actuator) system 545 or an actuator or other portion thereof is responsive to or controlled by variances in a relative positioning between the shaft 510 and the catheter sheath 512 (i.e., when part of the shaft 510 is received in the lumen 512d of the catheter sheath 512) to vary the length of at least part of cable 554b of the second Bowden cable 554 that extends from the first end 554a-1 of the sleeve 554a of the second Bowden cable. In this regard, in some embodiments, a control system (e.g., one or more components of system 100 or control system 322, such as controller 324) may be operatively coupled to an actuator system and operable to control activation of one or more actuators of the actuator system to vary the amount of length of a first part of the respective cable of each of the at least some of a plurality of Bowden cables that extends outwardly from the first end of the respective sleeve thereof during a change in a size, a shape, or both a size and a shape of the manipulable portion 502.

In some embodiments, the lumen of the sleeve 552a of the first Bowden cable 552 extends longitudinally in a particular direction from the first end 552a-1 of the sleeve 552a of the first Bowden cable 552, and the first part 554b-1 of cable 554b of the second Bowden cable 554 is physically or operatively coupled to the first Bowden cable 552 to cause at least the first end 552a-1 of the respective sleeve 552a of the first Bowden cable 552 to translate in a direction having a component parallel to this particular (longitudinal) direction (of the first Bowden cable 552) in response to, or at least during part of, the varying, caused by at least one actuator, of the amount of length of the first part 554b-1 of the cable 554b that extends outwardly from the first end 554a-1 of the respective sleeve 554a of the second Bowden cable 554. In some embodiments, at least one actuator (e.g., 556a, 556b, some other actuator or actuator set, or a portion of at least

84

one of these actuators) is physically or operatively coupled to the first Bowden cable 552 to cause the length of the first part 513b-1 of cable 513b that extends from the first end 552a-1 of the respective sleeve 552a of the first Bowden cable 552 to vary during at least part of the varying of the amount of length of the first part 554b-1 of the cable 554b of the second Bowden cable 554 that extends outwardly from the first end 554a-1 of the respective sleeve 554a of the second Bowden cable 554 caused by at least one actuator (e.g., 540b, 546, some other actuator or actuator set, or a portion of at least one of these actuators) in housing 520.

In FIGS. 7A and 7B, various portions of the receiver 529 (e.g., internal receiving mechanism 546) can be moved (e.g., pushed) proximally or moved (e.g., pulled) distally by the projection 528. For example, in some embodiments, internal receiving mechanism 546 is moved proximally by projection 528 when a first relative movement between catheter sheath 512 and a part of the shaft 510 received in the first lumen 512d causes a distance between a location on the part of the shaft 510 and a location on the catheter sheath 512 to decrease (for example, as the shaft 510 and sheath 512 are drawn together as shown in a sequence depicted consecutively by FIGS. 5D, 5E, and 5F). In some embodiments, internal receiving mechanism 546 is moved distally by projection 528 when a second relative movement between catheter sheath 512 and a part of the shaft 510 received in the first lumen 512d causes a distance between a location on the part of the shaft 510 and a location on the catheter sheath 512 to increase (for example, as the shaft 510 and sheath 512 are drawn apart as shown in a sequence depicted consecutively by FIGS. 5F, 5E, and 5D).

As shown in FIGS. 7A and 7B, internal receiving mechanism 546 may include a physically coupled slider mechanism 556 (which may be an example of an actuator or a particular actuator), portions of which are configured to move along guide 542d (also called out in FIG. 5R-1). In FIG. 5R-2, an aperture 557 in guide system 542 allows for a physical coupling between internal receiving mechanism 546 and slider mechanism 556. In some embodiments, internal receiving mechanism 546 is fixedly coupled to slider mechanism 556. In some embodiments, internal receiving mechanism 546 is releasably coupled to slider mechanism 556. In some embodiments, internal receiving mechanism 546 is configured to selectively couple to, or decouple from, slider mechanism 556 at one or more particular locations along a path of travel along guide 542c. For example, various mechanisms activatable at different locations along guide 542c can be employed to selectively couple or decouple internal receiving mechanism 556 respectively to or from slider mechanism 556 at the different positions or at other positions having a defined relationship to the different positions. In some embodiments, slider mechanism 556 includes various moveable portions including a first portion 556a (also referred to as master slider 556a in some embodiments) and a second portion 556b (also referred to as second sleeve slider 556b in some embodiments).

As shown in FIGS. 7A and 7B, the two sleeves 552a and 554a may be physically coupled (or, in some embodiments, fixedly coupled) to the second sleeve slider 556b. In various embodiments, second sleeve slider 556b is physically coupled to master slider 556a with a mechanism, such as with a tether 558, that delays a movement of master slider 556a until second sleeve slider 556b has been moved by a predetermined or defined amount or has moved to a predetermined or defined position.

In some embodiments associated with FIGS. 7A and 7B, the second sleeve slider **556b** (an example of a second moveable portion) is physically coupled to master slider **556a** (an example of a first moveable portion) by the tether **558**. In various embodiments, second sleeve slider **556b** can be moved proximally or distally by the projection **528** when the projection **528** repositions internal receiving mechanism **546** as described above in this disclosure.

In FIGS. 7A and 7B, master slider **556a** is located distally of second sleeve slider **556b**. In various embodiments, master slider **556a** and second sleeve slider **556b** are located on or guided by a same guide of guide system **542** (e.g., guide **542d**). In various embodiments, master slider **556a** is physically coupled to slave slider **548b** by second cable **554b**. In particular, a second part **554b-2** of cable **554b** of second Bowden cable **554** extending outwardly from a second end **554a-2** of second sleeve **554a** is physically coupled to master slider **556a** (which is an example of a first moveable portion of a particular actuator (e.g., slider mechanism **556**, internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators)). In some embodiments, a portion of the sleeve **554a** of the second Bowden cable **554** located at least proximate to the second end **554a-2** of the sleeve **554a** of the second Bowden cable **554** is physically coupled to the second sleeve slider **556b** (an example of a second moveable portion of a particular actuator (e.g., slider mechanism **556**, internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators)). In various embodiments associated with FIGS. 7A and 7B, each of the respective ends (represented by dots in FIGS. 7A and 7B) of second cable **554b** and each of the respective ends **554a-1** and **554a-2** of second sleeve **554a** are located at respective locations in housing **520**. In various embodiments associated with FIGS. 7A and 7B, each of the respective ends of cable **554b** and each of the respective ends **554a-1** and **554a-2** of second sleeve **554a** are located at respective locations outside a body when the manipulable portion **502** is located at a desired location within a bodily cavity in the body.

In various embodiments, master slider **556a** (which is an example of a first moveable portion of a particular actuator (e.g., slider mechanism **556**, internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators)) includes a locking device (not shown in FIGS. 5 and 7, but an example is illustrated in FIGS. 8A and 8B, which is described in more detail in this disclosure below) configured to restrict movement of master slider **556a** (e.g., along guide **542d**) when various forces suitable for translating master slider **556a** along guide **542d** are not applied to master slider **556a**. In some embodiments, this restricting of movement occurs during a varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554**. In some embodiments, the locking device (e.g., FIGS. 8A and 8B) is configured to allow movement of the master slider **556a** (an example of a first moveable portion) of the internal receiving mechanism **546** (an example of a particular actuator) after completion of a varying of a length of a part of cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554**.

In various embodiments, the locking device remains normally locked or fixedly coupled to a structure (e.g., guide **542d**) when various forces suitable for translating master slider **556a** along guide **542d** are not applied to master slider

556a. In various embodiments, master slider **556a** remains normally locked or secured to guide **542d** but is configured to move more freely when moved in one, but not both of the proximal and distal directions. For example, in various embodiments associated with FIGS. 7A and 7B, master slider **556a** is configured to move more freely when master slider **556a** is urged to move distally than when the master slider **556a** is urged to move proximally. In various embodiments, when master slider **556a** is subjected to an applied force that is directed distally, master slider **556a** will move relatively freely in the distal direction. When the applied force is removed, master slider **556a** will once again secure itself to the guide **542d**. In various embodiments, associated with FIGS. 7A and 7B, when a force (i.e., not applied by tether **558**) is applied to master slider **556a** in a proximal direction, master slider **556a** remains relatively fixed or secured to guide **542d**. That is, in these embodiments, while there is slack (or a tension level magnitude lower than a defined threshold) on the tether **558**, the master slider **556a** is restricted from being moved proximally (for example, under the influence of tension exerted by second cable **554b**). However, when there is a suitable tension (i.e., a tension level or magnitude at least equal to the defined threshold) on the tether **558**, the master slider **556a** unlocks from the guide **542d** and can be moved proximally in these embodiments. In other words, the locking device (e.g., FIGS. 8A and 8B) is configured to allow movement of the master slider **556a** (an example of a first moveable portion) of the internal receiving mechanism **546** (an example of a particular actuator) after the sleeve slider **556b** (an example of a second moveable portion) of the internal receiving mechanism **546** translates by a defined amount (e.g., a length of the tether **558**). If a magnitude or level of tension on tether **558** subsequently falls below the defined threshold, the master slider **556a** once again locks to guide **542d**. It is noted that although selective locking of master slider **556a** to guide **542d** has been described in these embodiments, master slider **556a** may be selectively locked to other structures (e.g., other guides of guide system **542**) in other embodiments.

Various mechanisms may be employed to provide the locking device(s) described above with respect to master slider **556a**. For example, a slider assembly **800** is schematically represented in FIGS. 8A and 8B. The slider assembly **800** includes a slider body **802** that is selectively moveable in a guide channel **804** (which, in some embodiments, may correspond to guide **542d**). In some embodiments, the slider body **802** may correspond to the master slider **556a** or be coupled to the master slider **556a**. A set of locking cams **806** (i.e., two cams in this illustrated embodiment) is provided in slider body **802**. Each of locking cams **806** may be pivotable about a respective pin **805**. A biasing member **808** (e.g., shown as a tension spring in FIGS. 8A, 8B) may be coupled to the locking cams **806** to urge each of the locking cams **806** to pivot about its respective pin **805** and cause a respective engagement surface **806a** of each locking cam **802** to engage with guide channel **804** as shown in FIG. 8A.

In various embodiments, the engagement surfaces **806a** are shaped to provide unidirectional self-locking characteristics. For example, in FIG. 8A, the engagement surfaces **806a** are shaped to cause the locking cams **806** to pivot inwardly and thereby reduce their locking or holding capability when a particular force is applied to move the slider body **802** distally (i.e., in the direction indicated as “◀ DISTAL” in FIG. 8A). Conversely, the shape of each of the engagement surfaces **806a** is configured to urge the

locking cams **806** to pivot outwardly and thereby increase locking or holding capability when a particular force is applied to move the slider body **802** proximally (i.e., in the direction indicated as “PROXIMAL ►” in FIG. 8A).

A tether **810** (which, in some embodiments, may correspond to the tether **558**) may be coupled to the set of locking cams **806** to selectively cause the locking cams **806** to pivot inwardly and unlock when a particular tension having a suitable magnitude to overcome the biasing action of biasing member **808** is applied to tether **810**. When the particular tension is applied to tether **810**, the slider body **802** can be moved proximally (i.e., in the direction indicated as “PROXIMAL ►”), for example, under the influence of tension provided by a cable member **812** (which, in some embodiments, may correspond to the cable **554b**) physically coupled to slider body **802** as shown in FIG. 8B.

Returning to FIGS. 7A and 7B, as projection **528** is inserted into the housing **520** and is received by receiver **529**, projection **528** may engage internal receiving mechanism **546** to cause internal receiving mechanism **546** to move (e.g., proximally in various embodiments) during the insertion. This movement in turn causes second sleeve slider **556b** to move (i.e., proximally in various embodiments). During the movement of second sleeve slider **556b**, an increasing distance develops between the moving second sleeve slider **556b** and the stationary master slider **556a**. It is noted that in various embodiments, master slider **556a** remains stationary at this time because master slider **556a** is locked in position, e.g., due to the locking mechanisms of FIG. 8. In various embodiments, an amount of length of the second part **554b-2** of second cable **554b** that extends from second end **554a-2** of second sleeve **554a** to master slider **556a** increases with the increasing distance between second sleeve slider **556b** and the stationary master slider **556a**. That is, increasing amounts of length of the second part **554b-2** of the second cable **554b** coupled to master slider **556a** are pulled out of sleeve **554a** with the increasing distance between second sleeve slider **556b** and the stationary master slider **556a**. This in turn, causes a varying of a length (e.g., a decrease in a length) of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554**.

It is noted that, in some embodiments such as those illustrated by FIGS. 7A and 7B, the second sleeve slider **556b** (an example of at least part of an actuator) is at least operatively coupled to the second Bowden cable **554** to translate the second end **554a-2** of sleeve **554a** of the second Bowden cable **554**, the second end **552a-2** of the sleeve **552a** of the first Bowden cable **552**, or each of the second end **554a-2** and the second end **552a-2** of the sleeve **552a** during at least part of a varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to the increasing distance between second sleeve slider **556b** and the stationary master slider **556a**).

It is also noted in various embodiments associated with FIGS. 7A and 7B, that an amount of translation undergone by an end or terminus of the second part **554b-2** of the cable **554b** of the second Bowden cable **554** at a particular time during a varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to an increase in distance between second sleeve slider **556b** and the stationary master slider **556a**) has a magnitude less than an amount

of translation undergone by the second end **554a-2** of sleeve **554a** of the second Bowden cable **554** at the particular time during the varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to the increase in distance between second sleeve slider **556b** and the stationary master slider **556a**).

It is also noted in various embodiments associated with FIGS. 7A and 7B, that an amount of translation undergone through the lumen of the sleeve **552a** of the first Bowden cable **552** by a portion of the cable **513** of the first Bowden cable **552** at a particular time during a varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to an increase in distance between second sleeve slider **556b** and the stationary master slider **556a**) is at least substantially equal in magnitude to an amount of translation undergone through the lumen of the sleeve **554a** of the second Bowden cable **554** by a portion of the cable **554b** of the second Bowden cable **554** at the particular time during the varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to the increase in distance between second sleeve slider **556b** and the stationary master slider **556a**).

A third Bowden cable may be employed in some embodiments. For example, a third Bowden cable **555** other than at least the second Bowden cable **554** may be employed in various embodiments. For example, control element **513** may, in some embodiments, provide a third Bowden cable **555** made up of sleeve **513a** and cable **513b**. It is also noted in various embodiments associated with FIGS. 7A and 7B, (and described in greater detail later in this disclosure) that an amount of translation undergone through the lumen of the sleeve **513a** of the third Bowden cable **555** by a portion of the cable **513b** of the third Bowden cable **555** at a particular time during a varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to an increase in distance between second sleeve slider **556b** and the stationary master slider **556a**) is greater in magnitude than an amount of translation undergone through the lumen of the sleeve **554a** of the second Bowden cable **554** by a portion of the cable **554b** of the second Bowden cable **554** at the particular time during the varying of the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of the sleeve **554a** of the second Bowden cable **554** (e.g., due to the increase in distance between second sleeve slider **556b** and the stationary master slider **556a**). In this illustrated embodiment, the first Bowden cable **552** and the third Bowden cable **555** provided by control element **513** have different respective sleeves but share a common or same cable (i.e., cable **513b**). In other embodiments, a third Bowden cable may be distinct from control element **513**.

In some embodiments, such as those illustrated by FIGS. 7A and 7B, the second sleeve slider **556b** (an example of an actuator) is at least operatively coupled to the first Bowden cable **552** to cause a change (e.g., an increase or decrease) in an amount of the length (e.g., due to the relative movement between the second sleeve slider **556b** and the stationary master slider **556a**) of the first part **513b-1** of the cable **513** of the first Bowden cable **552** that extends outwardly

from the first end **552a-1** of sleeve **552a** during at least part of a varying (e.g., due to the relative movement between the second sleeve slider **556b** and the stationary master slider **556a**) of the length of the first part **554b-1** of the respective cable **554b** of the second Bowden cable **554** that extends outwardly from the first end **554a-1** of sleeve **554**.

In some embodiments associated with FIGS. 7A and 7B, each of the second end **554a-2** of the second sleeve **554** and the second end **552a-2** of the sleeve **552a** translates during at least part of the varying of the length of the first part **554b-1** of the respective cable **554b** that extends outwardly from the first end **554a-1** of second sleeve **554a**.

Since the second cable **554b** is physically coupled to slave slider **548b** (i.e., via the first part **554b-1** of cable **554b**), the slave slider **548b** is also moved (i.e., proximally in this illustrated embodiment) relative to sleeve slider **548a** during the relative movement between second sleeve slider **556b** and the stationary master slider **556a**.

While the second sleeve slider **556b** moves proximally, away from the stationary master slider **556a** with a particular rate (e.g., under the pushing influence from the projection **528**), the control element **513** is metered with a relatively faster rate (e.g., the 2× rate in some embodiments) discussed herein with respect to FIG. 6, according to some embodiments. Typically, in various embodiments, this movement of the second sleeve slider **556b** away from the stationary master slider **556a**, and its accompanying control element faster metering rate, occurs while the manipulable portion **502** is being advanced outwardly from the distal end **512b** of the catheter sheath **512** due to a relative movement between the shaft **510** and the catheter sheath **512**. In some embodiments, this faster metering rate is due to the occurrence of two concurrent movements. The first of the two concurrent movements is a movement of a portion of the first Bowden cable **552** (e.g., at least the first end **552a-1** of its sleeve **552a** together with its cable **513b**) proximally due to the proximal movement of the slave slider **548b**. The second of the two concurrent movements is a relative movement between the cable **513b** of the first Bowden cable **552** and the sleeve **552a** of the first Bowden cable **552** due to a proximal movement of at least the second end **552a-2** of sleeve **552** (e.g., due to proximal movement of the second sleeve slider **556b**). The combination of the first and second of the two concurrent movements causes the faster control cable metering rate (e.g., the 2× rate in some embodiments).

However, as the second sleeve slider **556b** continues to translate proximally under the influence of the pushing from the projection **528**, in some embodiments, the distance between the master slider **556a** and the second sleeve slider **556b** reaches a defined amount sufficient to remove slack in tether **558** (or **810**) and allow tether **558** (or **810**) to be sufficiently tensioned to cause the master slider **556a** to unlock (e.g., by way of a locking/unlocking device of FIG. 8) and move along guide channel **542d** (or **804**). Upon unlocking, master slider **556a** is moveable (i.e., proximally in this illustrated embodiment) by further movement of second sleeve slider **556b** (i.e., proximally in this illustrated embodiment), and, since there is no more relative movement between the master slider **556a** and the second sleeve slider **556b** (i.e., the master slider **556a** is in an unlocked state), the cable **554b** of the second Bowden cable **554** no longer moves relative to its sleeve **554a** (e.g., FIG. 7B). Consequently, the first of the above-discussed two concurrent movements no longer exists, thereby leaving only the movement of the cable **513b** through sleeve **552a** as the second sleeve slider **556b** continues to move proximally while pulling the master slider **556a** with it. Without the movement

of the first end **552a-1** of the sleeve **552a** of the first Bowden cable **552** in this tensioned-tether state, the control element metering rate drops to a relatively slower rate (e.g., the 1× rate in some embodiments) discussed herein with respect to FIG. 6, according to some embodiments. In various embodiments of FIGS. 7A and 7B, sleeve slider **548a** remains stationary during the associated movements.

In some embodiments, the tensioned-tether state (e.g., FIG. 7B) causes the slave slider **548b** to cease moving relative to the sleeve slider **548a**. In some embodiments, tether **558** acts as a stop configured to restrict at least the slave slider **548b** from being translated by more than a maximum amount. In some embodiments, tether **558** acts as a stop configured to restrict at least the first end **552a-1** of sleeve **552a** from being translated by more than a predetermined or defined amount. In various embodiments, the control system (which also may be referred to as an actuator system in some embodiments) **545**, in a particular state in which the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** has been translated by a predetermined amount, causes the first Bowden cable **552** to vary the length of the first part **513b-1** of cable **513b** of the first Bowden cable **552** that extends outwardly from the first end **552a-1** of sleeve **552a** of the first Bowden cable **552**, and causes the second Bowden cable **554** to cease varying the length of the first part **554b-1** of the cable **554b** of the second Bowden cable **554** during a varying of the length of the first part **513b-1** of cable **513b** of the first Bowden cable **552** that extends outwardly from the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** after at least the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** has translated by the predetermined amount. The predetermined amount may be an amount of or related to a distance between the master slider **556a** and second sleeve slider **556b** in which tension in the tether **558** reaches a predetermined threshold. In addition, in some embodiments, in the particular state in which the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** has been translated by the predetermined amount, the control system (which also may be referred to as an actuator system in some embodiments) **545** causes at least the second end **554a-2** of the sleeve **554a** of the second Bowden cable **554** to translate during the varying of the length of the first part **513b-1** of cable **513b** of the first Bowden cable **552** that extends outwardly from the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** after at least the first end **552a-1** of sleeve **552a** of the first Bowden cable **552** has translated by the predetermined amount.

In FIGS. 7 and 8 tethers **558**, **810** may be provided by a flexible element (e.g., a flexible cable or line) according to various embodiments. In other embodiments other forms of tethers may be employed including by way of non-limiting example, telescoping members that can telescope between predetermined minimum and maximum extents. In other embodiments, other tethers may be provided by a pin-in-channel type coupling in which a pin is physically coupled to a first member and the channel is coupled to a second member, and relative movement between the first and second members is controlled by various stop features that limit movement of the channel.

In some embodiments, the particular state is a state in which the second end **554a-2** of sleeve **554a** of the second Bowden cable **554** has been translated by a predetermined amount (e.g., with respect to the master slider **556a**). In some embodiments, the particular state is a state in which the length of the first part **554b-1** of the respective cable **554b** of the second Bowden cable **554** that extends out-

91

wardly from the first end **554a-1** of the respective sleeve **554a** of the second Bowden cable **554** has been varied by a predetermined amount.

It is noted in various embodiments, when the relative movement of the projection **528** relative to the housing **520** changes direction, the movement of the second sleeve slider **556b** also changes direction. For example, when the movement of the projection **528** is changed from moving proximally to moving distally, the second sleeve slider **556b** is also changed to move distally, thereby reducing tension on the tether **558** (or **810**) and causing master slider **556a** to lock (e.g., by the locking mechanism of FIG. **8**) and thereby restrict movement thereof along guide **542d** (or **804**) in the proximal direction. In this case, the relative movement between the second sleeve slider **556b** and the now stationary master slider **556a** can cause a reduction of an amount of length of the second part **554b-2** of the cable **554b** as the distance between the second end **554a-2** of sleeve **554a** and the master slider **556a** reduces. The reduction in the amount of length of the second part **554b-2** of the cable **554b** causes an increase in an amount of length of the first part **554b-1** of cable **554b** (e.g., an increase in length thereof which reduces tension in the first part **554b-1** of cable **554b**), which in turn allows the slave slider **548b** to move distally under the influence of a reactive force provided by sleeve **552a** due to tension in control cable **513b**. In various embodiments, distal movement of a portion of cable **513b** outwardly from housing **520** accompanies distal movement of the slave slider **548b**. In various embodiments, play-out of a portion of cable **513b** outwardly from housing **520** accompanies distal movement of the slave slider **548b**.

In various embodiments, the distal movement of slave slider **548b** continues until the second sleeve slider **556b** and the master slider **556a** come into contact. At that point, further distal movement of the second sleeve slider **556b** pushes the master slider **556a** distally. A lack of relative movement between the master slider **556a** and the second sleeve slider **556b** results in no movement of the slave slider **548b** relative to sleeve slider **548a**. In some embodiments, as the second sleeve slider **556b** pushes the master slider **556a** distally, a reduction in the amount of length of the second part **513b-2** of control cable **513b** occurs, which in turn, allows for a distal movement of a portion of cable **513b** outwardly from housing **520**. In some embodiments, as the second sleeve slider **556b** pushes the master slider **556a** distally, a reduction in the amount of length of the second part **513b-2** of control cable **513b** occurs, which in turn, allows for a play-out of a portion of cable **513b** outwardly from housing **520**.

Withdrawal of the projection **528** from the housing **520** accompanies a distal movement of the internal receiving mechanism **556**, according to some embodiments. In this state, in some embodiments, the second sleeve slider **556b** moves toward the master slider **556a**, releasing tension in the tether **558** and causing both of the above-discussed two concurrent movements (albeit distally, not proximally), and a relatively faster control element metering rate (e.g., the 2× rate in some embodiments). When the distal movement of the second sleeve slider **556b** causes second sleeve slider **556b** to come into contact with the master slider **556a**, master slider **556a** is pushed distally. In this state, both the second sleeve slider **556b** and the master slider **556a** move together distally, so that little or no relative movement occurs between the cable **554b** and sleeve **554a** of the second Bowden cable **554**, leaving only or primarily, the movement of cable **513b** relative to sleeve **552a**. Without the relative movement occurring between the cable **554b** and

92

sleeve **554a** of the second Bowden cable **554**, the control element metering rate drops to a relatively slower rate (e.g., the 1× rate in some embodiments) discussed herein with respect to FIG. **6**, according to some embodiments. In various embodiments, sleeve slider **548a** remains stationary during these movements.

It is noted in various embodiments that when the second sleeve slider **556b** moves distally or proximally in a manner where a relative positioning between the second sleeve slider **556b** and the master slider **556a** is changing, the slave slider **548b** is caused to move in the same direction of travel as the second sleeve slider **556b**. When the second sleeve slider **556b** moves distally or proximally in a manner where a relative positioning between the second sleeve slider **556b** and the master slider **556a** is not changing (e.g., when the master slider **556a** moves along with the second sleeve slider **556b**), the slave slider **548b** does not move relative to sleeve slider **548a**.

In various embodiments described above, the movement of the projection **528** relative to the housing **520** moves at least a portion of an actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) in a first direction (e.g., proximally along a linear path as defined in FIGS. **7A** and **7B**) and may be employed during manipulation or metering movement of at least a portion of cable **513b** (an example of an elongated control element in some embodiments) in a manner that is the same or similar to that described with the take-up of the control line associated with line **602** in FIG. **6**. When the relative movement of the projection **528** relative to the housing member **520** changes direction, the portion of the actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) moves in a second direction different than (e.g., opposite) the first direction (e.g., distally along a linear path as defined in FIGS. **7A** and **7B**) and may be employed during manipulation or metering movement of cable **513b** in a manner that is the same or similar to that described with the play-out of the control line associated with line **604** in FIG. **6**. In various embodiments, movement of the portion of the actuator in the first direction is associated with an amount of the length **528a** of projection **528** within receiver **529** increasing in magnitude, while movement of the portion of the actuator in the second direction is associated with an amount of the length **528a** of projection **528** within receiver **529** decreasing in magnitude. In some embodiments, movement of the portion of the actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) in the first direction is associated with a transition of the manipulable portion **502**, at least in part, toward or to an expanded configuration, while movement of the portion of the actuator in the second direction is associated with a transition of the manipulable portion **502**, at least in part, toward or to a delivery configuration.

In various embodiments, the actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) is operatively coupled to the cable **513b** (an example of at least a portion of an elongated control element) to cause an increase and a subsequent decrease in an amount of the length of the cable **513b** located outside of the distal end **512b** of catheter sheath **512** when at least the portion of the actuator moves in the first direction (e.g., proximally as defined in FIGS. **7A** and **7B**), which may, in some embodiments, accompany or be required by an advancement of manipulable portion **502** outwardly from the distal end **512b**

of the catheter sheath **512**, as shown by the sequence represented consecutively in FIGS. **5H**, **5I** and **5J**. In this regard, in some embodiments, at least a portion of the actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) is moveable (and, in some embodiments, is selectively moveable, e.g., by way of the projection **528**, or by relative movement between shaft **510** and catheter sheath **512**) in each of one particular direction (e.g., the first direction) and a second direction different than the one particular direction (e.g., the first direction) to manipulate at least the portion of the cable **513b** (an example of at least part of a control element). This movement of at least the portion of the actuator in each of the first direction and the second direction may be with respect to the housing **520**.

In various embodiments, the actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) is operatively coupled (to the cable **513b** (an example of at least part of an elongated control element) to cause an increase and a subsequent decrease in an amount of the length of the cable **513b** located outside of the distal end **512b** of catheter sheath **512** when at least the portion of the actuator moves in the second direction (e.g., distally as defined in FIGS. **7A** and **7B**), which may, in some embodiments, accompany or be required by a retraction of manipulable portion **502** into the distal end **512b** of the catheter sheath **512**, as shown by the sequence represented consecutively in FIGS. **5J**, **5I** and **5H**.

In some embodiments, a modulation actuator (e.g., second particular actuator **540b**, some other actuator or actuator set, or a portion of at least one of these actuators) may be physically or operatively coupled to the manipulable portion **502** to modulate at least a size, a shape, or both a size and a shape of the manipulable portion **502**, e.g., at least in a state where at least a part of the manipulable portion **502** and a part of the cable **513b** (an example of at least part of a control element) extends outside of the distal end **512b** of the catheter sheath **512** (e.g., FIG. **5C**). In some embodiments, the modulation actuator is operable to selectively move at least in part (e.g., by way of the projection **528**, or relative movement between shaft **510** and catheter sheath **512**) the manipulable portion **502** between a delivery configuration in which the manipulable portion **502** is sized, shaped, or both sized and shaped to be delivered through the first lumen **512d** of the catheter sheath **512** and an expanded configuration in which the manipulable portion **502** is sized, shaped, or both sized and shaped too large for delivery through the first lumen **512d** of the catheter sheath **512**.

In some embodiments, the control system (e.g., an actuator system in some embodiments) **545**, or one or more components of system **100** or control system **322**, such as controller **324**) may be physically or operatively coupled to or include the actuator (e.g., the internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators), and may be configured to cause the actuator (e.g., the internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) to manipulate at least the portion of the cable **513b** (e.g., at least part of a control element) to cause a length of the part of the cable **513b** extending outside the distal end **512b** of the catheter sheath **512** to increase and then subsequently decrease during or throughout a movement of at least the portion of the actuator in the one particular direction (e.g., in the first direction, proximal direction causing the advancement sequence of FIGS. **5H**, **5I**, **5J** or in the second, distal direction causing the retraction

sequence of FIGS. **5J**, **5I**, **5H**). The movement of at least a portion of the actuator (e.g., the internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) in the one particular direction may be associated with a relative movement between the shaft **510** and the catheter sheath **512**, when part of the shaft **510** is located in the lumen **512d** of the catheter sheath **512**. In some of these embodiments, a part of the manipulable portion **502** extends outside the distal end **512b** of the catheter sheath **512** and has a size, a shape, or both a size and a shape too large to fit in the lumen of the catheter sheath (for example, as shown in FIGS. **5I** and **5J**) during or throughout the movement of at least the portion of the actuator in the one particular direction. In some of these embodiments, cable **513b** is located, at least in part, in the lumen **512d** of catheter sheath **512** during the movement of at least the portion of the actuator in the one particular direction. In some of these embodiments, shaft **510** is located at least in part, in the lumen **512d** of catheter sheath **512** during the movement of at least the portion of the actuator in the one particular direction. In some embodiments, such control system **545** may be configured to cause the modulation actuator to modulate the manipulable portion **502**, such that a part of the manipulable portion **502** extending outside the distal end **512b** of the catheter sheath **512** has a size, a shape, or both a size and a shape too large to fit in the lumen **512d** of the catheter sheath **512** (for example, as shown in FIGS. **5I** and **5J**) during or throughout the movement of at least a portion of the actuator (e.g., the internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) in the one particular direction.

In some embodiments, the actuator and the modulation actuator are the same device, or the actuator includes the modulation actuator. For example, the actuator may be the internal receiving mechanism **546**, and the modulation actuator may be the master slider **556a** or the sleeve slider **556b** of the internal receiving mechanism **546**. In this regard, it should be noted that the present invention is not limited to any particular actuator configuration. For example, although the internal receiving mechanism **546** is identified in some examples above as an actuator, any other component of catheter system **500** that achieves a desired function or result may alternatively be considered an actuator. For instance, although the internal receiving mechanism **546** may be deemed an actuator configured to move along a linear path when moving in the first direction (e.g., proximal direction in FIG. **7**) or in the second direction (e.g., distal direction in FIG. **7**), a portion of cable **554b**, sleeve **554a**, or each of the cable **554b** and sleeve **554a** may be considered a portion of such actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) due to their operative coupling, such that the portion of cable **554b**, sleeve **554a**, or each of the cable **554b** and sleeve **554a** follows an arcuate or coiled path (e.g., FIGS. **7A** and **7B**) when the internal receiving mechanism **546** is moving in the first direction (e.g., proximal direction in FIG. **7**) or in the second direction (e.g., distal direction in FIG. **7**).

In various embodiments, the amount of cable **513b** within the housing **520** will vary in accordance with the movement of projection **528** when received by receiver **529**. It is further noted that the amount of the portion **514** of cable **513b** extending outwardly from the distal end **512b** of the catheter sheath **512** will vary inversely (e.g., linearly or non-linearly) with an increase or decrease in an amount of the cable **513** located within the housing **520**. In various embodiments, when movement of the projection **528** causes the second

sleeve slider **556b** to move distally or proximally in a manner where a relative positioning between the second sleeve slider **556b** and the master slider **556a** is changing, take-up of cable **513b** (e.g., occurring during insertion of projection **528** inwardly into receiver **529**) or play-out (e.g., occurring during retraction of projection **528** outwardly from receiver **529**) occurs at a 2:1 ratio with the movement of the projection **528**. This occurs because the slave slider **548b** moves concurrently with the movement of the second sleeve slider **556b** relative to the stationary master slider **556a**. When movement of the projection **528** causes the second sleeve slider **556b** to move distally or proximally in a manner where a relative positioning between the second sleeve slider **556b** and the master slider **556a** is not changing, take-up of cable **513b** (e.g., occurring during insertion of projection **528** inwardly into receiver **529**) or play-out of cable **513b** (e.g., occurring during retraction of projection **528** outwardly from receiver **529**) occurs at a 1:1 ratio with the movement of the projection **528**. This occurs because the slave slider **548b** does not move relatively to sleeve slider **548a** during this movement.

It is understood that in various embodiments, the actual rate that cable **513b** is metered during take-up or play-out is dependent on the actual rate of relative movement between projection **528** and receiver **529**. That is, in various embodiments a defined speed ratio between the metering rate of cable **513b** and the rate of relative movement between projection **528** and receiver **529** controls the actual metering rate of control cable **513b**. The speed ratio specifies an output speed associated with an output portion of a particular device as a function of an input speed associated with an input portion of the particular device. It is noted in FIGS. **7A** and **7B**, that although a portion of a control element manipulation actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) moves along an essentially linear path during the take-up or play-out of cable **513b**, the invention is not so limited, and the portion of the actuator may move along an arcuate path during the take-up or play-out of cable **513b** in other embodiments.

In some embodiments, control system **545** is physically or operatively coupled to at least one control element manipulation actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) to control at least the actuator to cause movement of at least a portion of an elongated control element (e.g., cable **513b**), e.g., along a path extending toward the manipulable portion **502**, by metering the portion of the elongated control element with (a) a first rate of movement in response to at least a portion of the control element manipulation actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) moving (e.g., with respect to the housing **520**) with a particular rate of movement in a first direction (e.g., proximally as defined in FIGS. **7A** and **7B**), and (b) a second rate of movement in response to the at least a portion of the control element manipulation actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) moving (e.g., with respect to the housing **520**) with the same particular rate of movement in a second direction different than the first direction (e.g., distally as defined in FIGS. **7A** and **7B**), such that a first ratio of the first rate of movement to the particular rate of movement is different than a second ratio of the second rate of movement to the particular rate of movement, e.g., when a portion of

cable **513b** (an example of an elongated control element in some embodiments) is positioned at a particular location.

In various embodiments, a modulation actuator is operable to selectively move manipulable portion **502** or structure **502a** thereof between a delivery configuration in which manipulable portion **502** or structure **502a** thereof is sized or shaped to be delivered through a bodily opening leading to a bodily cavity and an expanded configuration in which the manipulable portion **502** or structure **502a** thereof is sized or shaped too large for delivery through the bodily opening. In some of these various embodiments, such as those described above with respect to FIG. **6**, control system **545** controls at least one control element manipulation actuator by switching a ratio of (a) a rate at which the portion of the elongated control element (e.g., cable **513b**) is metered to (b) a rate of movement of at least the portion of the control element manipulation actuator (e.g., internal receiving mechanism **546**, some other actuator or actuator set, or a portion of at least one of these actuators) between each ratio of a first set of two or more different predetermined ratios when the modulation actuator transitions the manipulable portion **502** from the delivery configuration to the expanded configuration. On the other hand, in some embodiments, the control system **545** controls the control element manipulation actuator to vary movement of the control element by switching the ratio of (a) to (b) between each ratio of a second set of two or more different predetermined ratios when the modulation actuator transitions the manipulable portion **502** from the expanded configuration to the delivery configuration. In some of these various embodiments, the first ratio is a member of the first set and the second ratio is member of the second set. In some embodiments, at least one of the predetermined ratios in the first set is the same as one of the predetermined ratios in the second set. In some embodiments, at least two of the predetermined ratios in the first set are the same as at least two of the predetermined ratios in the second set.

For example, in FIG. **6**, the control line is metered with a first set of two different predetermined rates (i.e., line **602**) during take-up of the control line and is metered with a second set of two different predetermined rates (i.e., line **604**) during play-out of the control line. When a particular amount of the associated structure is located outside the distal end of the catheter sheath (e.g., a particular amount represented by 70 mm on the horizontal axis), the control line is metered with a first rate of the first set during control line take-up (i.e., portion **602b** of line **602**) that is different (e.g., twice the rate) than a second rate of the second set that the control line is metered with during control line play-out (i.e., portion **604c** of line **604**). When the metering rate of the control element is dependent on a given rate of movement of the portion of the control line manipulation actuator in each of the metering directions (for example, as described with respect to FIGS. **7A** and **7B**), each of the predetermined rates in each of the first and second sets can be expressed as a ratio of the predetermined rate to the rate of movement of the portion of the control line manipulation actuator when the portion of the control line manipulation actuator is moved in each of different directions with the same rate of movement.

Stated another way, in various embodiments, a modulation actuator is operable to selectively move manipulable portion **502** or structure **502a** thereof between a delivery configuration in which manipulable portion **502** or structure **502a** thereof is sized or shaped to be delivered through a bodily opening leading to a bodily cavity and an expanded configuration in which the manipulable portion **502** or structure **502a** thereof is sized or shaped too large for

delivery through the bodily opening. In some of these various embodiments, such as those described above with respect to FIG. 6, control system 545 controls at least one control element manipulation actuator by switching a ratio of (a) a rate at which the portion of the elongated control element (e.g., cable 513b) is metered to (b) a rate of movement of at least the portion of the control element manipulation actuator (e.g., internal receiving mechanism 546, some other actuator or actuator set, or a portion of at least one of these actuators) between each ratio of a first set of two or more different ratios when the modulation actuator transitions the manipulable portion 502 from the delivery configuration to the expanded configuration. In some embodiments, each ratio in the first set of two or more different ratios has a value corresponding to a respective one of a first set of two or more different predetermined values. On the other hand, in some embodiments, the control system 545 controls the control element manipulation actuator to vary movement of the control element by switching the ratio of (a) to (b) between each ratio of a second set of two or more different ratios when the modulation actuator transitions the manipulable portion 502 from the expanded configuration to the delivery configuration. In some embodiments, each ratio in the second set of two or more different ratios has a value corresponding to a respective one of a second set of two or more different predetermined values. In some embodiments, the first ratio is a member of the first set of two or more different ratios and the second ratio is member of the second set of two or more different ratios. In some embodiments, at least one of the predetermined ratios in the first set is the same as one of the predetermined ratios in the second set. In some embodiments, at least two of the predetermined ratios in the first set are the same as at least two of the predetermined ratios in the second set.

In some embodiments, the particular amount of the associated structure (e.g., the structure 502a of the manipulable portion 502) located outside the distal end 512b of the catheter sheath 512 is a particular size of the manipulable portion 502 or structure 502a thereof between the distal end 512b and the distal end of the manipulable portion 502. In some embodiments, the particular amount of the manipulable portion 502 or structure 502a thereof located outside the distal end 512b of the catheter sheath 512 is a particular length of the manipulable portion 502 or structure 502a thereof extending from the distal end 512b to the distal end of the manipulable portion 502 or structure 502a thereof. In some embodiments, the particular amount of the manipulable portion 502 or structure 502a thereof located outside the distal end 512b of the catheter sheath 512 is a particular length of the manipulable portion 502 or structure 502a thereof extending along a surface of the manipulable portion 502 or structure 502a thereof from the distal end 512b to the distal end of the manipulable portion 502 or structure 502a thereof. In some embodiments, the particular amount of the manipulable portion 502 or structure 502a thereof located outside the distal end 512b of the catheter sheath 512 is a surface area or volume of a part of the manipulable portion 502 or structure 502a thereof located outside the distal end 512b of the catheter sheath 512. In some embodiments, a particular amount of the manipulable portion 502 or structure 502a thereof extending outwardly from the distal end 512b of catheter sheath 512 corresponds to a particular amount of the length 528b of projection 528 being received in receiver 529 (for example as shown in FIGS. 7A and 7B). In some embodiments where the control line metering scheme depicted in FIG. 6 is employed, a control system (e.g., control system 545, or one or more components of

system 100 or control system 322, such as controller 324) may be configured to control at least a control line manipulation actuator that is the same or similar to that represented in FIGS. 7A and 7B, when a particular amount of length 528b of projection 528 is received within receiver 529 during a transition of the manipulable portion 502 toward or to an expanded configuration, to cause cable 513b (an example of at least part of a control element or cable) to be metered with a first rate. On the other hand, in some embodiments, the control system may be configured to control at least the control line manipulation actuator, when the same particular amount of length 528b of projection 528 is received within receiver 529 during a transition of the manipulable portion 502 toward or to a delivery configuration, to cause control cable 513b to be metered with a second rate different than the first rate.

When the control line metering scheme depicted in FIG. 6 is employed by a control line manipulation actuator that is the same or similar to that represented in FIGS. 7A and 7B, each of portion 602b of line 602 and portion 604b of line 604 may be associated with a condition in which a relative positioning between the second sleeve slider 556b and the master slider 556a is changing, while each of portion of 602c of line 602 and portion 604c of line 604 may be associated with a condition in which a relative positioning between the second sleeve slider 556b and the master slider 556a is not changing. Accordingly a control loop that is the same or similar to that created by portions 602b, 602c, 604b and 604c may be established by the control system 545 for the metering of cable 513b as the manipulable portion 502 is advanced outwardly from the distal end 512b of catheter sheath 512 into an expanded configuration that is the same or similar to that shown in FIG. 5J and then subsequently retracted back into the confines of first lumen 512d (e.g., into a delivery configuration). It is noted in some embodiments, that metering action of the control line manipulation actuator represented in FIGS. 7A and 7B may in some cases be interrupted at various points along the control loop prior to a completion of an advancement of the manipulable portion 502 into the expanded configuration or prior to a completion of a retraction of the manipulable portion 502 back into the confines of first lumen 512d. The interruption may be motivated, for example, by a user decision to reverse a movement of manipulable portion 502 to (a) retract the manipulable portion 502 rather than proceeding with the advancement of the manipulable portion 502 toward or to the expanded configuration, or (b) advance the manipulable portion rather than proceeding with the retraction of the manipulable portion 502 into the confines of the first lumen 512d. In either case, a change in a metering direction of cable 513b is typically required during the reversal of movement of manipulable portion 502 caused by the interruption.

A required change in the metering direction of cable 513b may be motivated for various reasons including occurrences of slack or undesired level of tension in the cable 513b as described above in this disclosure. In various embodiments, an employed control element metering system (e.g., such as that represented in FIGS. 7A and 7B) is configured to, when interrupted from metering a portion of a control element (e.g., cable 513b) in a first particular metering direction to metering the portion of the control element in a second particular metering direction different than the first particular metering direction, cause a defined or predetermined change in metering rate to accompany the change in metering direction. That is, when the portion of the control element is interrupted from being metered with a first rate in

a first metering direction to being metered in a second metering direction different than the first metering direction, the control element metering system can cause the portion of the control element to be metered with a second rate in the second metering direction, the second rate being different than the first rate. This mode of operation can occur at various points along the control loop. For example in FIG. 6, the control line is being metered with a first rate in a first metering direction (e.g., a take-up direction) associated with a portion 602c of line 602. If the metering of the control line along portion 602c in the first metering direction is interrupted and metered in a second different metering direction (e.g., a play-out direction) before less than an intended amount of the device has been advanced outwardly from the distal end of the catheter sheath (for example, when only approximately 150 mm of the device has been advanced outwardly from the catheter sheath), the control line is not metered in the second metering direction with the first rate, but rather a second rate represented by line 606. In various embodiments, the second rate is the same as the metering rate associated with portion 604b of line 604. Advantageously, these various embodiments allow for the device to be manipulated in a particular desired manner that may be required by the change in the metering direction during the interrupted cycle.

In various embodiments associated with FIGS. 5 and 7, control system 545 is configured to cause movement of a portion of control element 513 (e.g., cable 513b) along a path extending toward manipulable portion 502. Control system 545 may be further configured to, when a portion of the control element 513 is located at a particular position along the path, (a) meter movement of the portion of the control element 513 at a first rate in a first direction along the path away from the particular position at least in response to occurrence of a first state that triggers a transition of the manipulable portion 502 toward or to the expanded configuration, and (b) meter movement of the portion of the control element 513 at a second rate in a second direction along the path away from the particular position at least in response to occurrence of a second state that triggers a transition of the manipulable portion 502 toward or to the delivery configuration. In some embodiments, the second direction along the path is different than the first direction along the path and the second rate is different than the first rate.

In some embodiments, control system 545 is configured, when a particular amount of the manipulable portion 502 is located outside the distal end 512b of the catheter sheath 512 during a transition of the manipulable portion 502 toward or to the expanded configuration, to control an actuator to cause (a) control element 513 to have a first amount of length located outside the distal end 512b of the catheter sheath 512, at least in response to occurrence of a first state that triggers a transition of the manipulable portion 502 toward or to the expanded configuration, and when the same particular amount of the manipulable portion 502 is located outside the distal end 512b of the catheter sheath 512 during a transition of the manipulable portion 502 toward or to the delivery configuration, to control the actuator to cause (b) control element 513 to have a second amount of length located outside the distal end 512b of the catheter sheath 512, at least in response to occurrence of a second state that triggers a transition of the manipulable portion 502 toward or to the delivery configuration. In various ones of these embodiments, the first amount of length is different than the second amount of length.

In some embodiments, control system 545 is configured, when a particular relative positioning exists between the catheter sheath 512 and the shaft 510 received in the first lumen 512d of the catheter sheath 512 during a transition of the manipulable portion 502 toward or to the expanded configuration, to control an actuator to cause (a) control element 513 to have a first amount of length located outside the distal end 512b of the catheter sheath 512, at least in response to occurrence of a first state that triggers a transition of the manipulable portion 502 toward or to the expanded configuration, and when the same particular relative positioning exists between the catheter sheath 512 and the shaft 510 received in the first lumen 512d of the catheter sheath 512 during a transition of the manipulable portion 502 toward or to the delivery configuration, to control the actuator to cause (b) control element 513 to have a second amount of length located outside the distal end 512b of the catheter sheath 512, at least in response to occurrence of a second state that triggers a transition of the manipulable portion 502 toward or to the delivery configuration. In various ones of these embodiments, the first amount of length is different than the second amount of length. The particular relative positioning may be a relative longitudinal positioning in some embodiments.

The first and the second states described above can take different forms in various embodiments. For example, the first state may be associated with a direction of relative moment between catheter shaft 512 and a portion of shaft 510 in first lumen 512d that decreases a distance between a location on catheter sheath 512 and a location on shaft 510 and the second state may be associated with a direction of relative moment between catheter shaft 512 and a portion of shaft 510 in first lumen 512d that increases a distance between a location on catheter sheath 512 and a location on shaft 510.

In some embodiments associated with FIGS. 7A and 7B, after leaving the confines of the sleeve 552a, the second part 513b-2 of cable 513b is subjected to a bend (e.g., a 180 degree bend) in a guide 560 before coupling to the forming slider 561 associated with first particular actuator 540a. In various embodiments, guide 560 is relatively rigid in form and does not flex like sleeves 552 and 554. The use of guide 560 may be motivated by various reasons including imparting a serpentine path to the cable 513b to reduce an overall size of housing 520 or additionally or alternatively, guiding cable 513b to another guide in guide system 542 or additionally or alternatively, changing an activation direction of forming slider 561. Forming slider 561 may be configured to move along guide 542a. The operation of forming slider 561 is described later in this disclosure.

FIGS. 5S-1, 5S-2, 5S-3, 5S-4, 5S-5, and 5S-6 (collectively FIG. 5S) are top plan views of various actuator sets associated with catheter system 500, various ones of the actuators in the sets positioned in particular activation positions associated with different particular states of the expanded configuration of manipulable portion 502 according to various embodiments. In some embodiments, various ones of the actuator sets may include one or more actuators selectively moveable between at least two different activation positions. For example, an actuator may be selectively moveable from a respective first activation position into a second activation position to change a size, a shape, or both a size and a shape of an expanded configuration of manipulable portion 502 from one particular state to another particular state. In various embodiments, an actuator set (e.g., first actuator set 540) may include two or more actuators, each of the actuators in the actuator set independently or

101

separately moveable from the other actuators in the actuator set from a respective first activation position into a respective second activation position to independently change a size, a shape, or both a size and a shape of an expanded configuration of manipulable portion **502** from one particular state into another particular state. It is noted in at least some of the embodiments of FIG. **5S** that shaft **510** (not called out) is inserted into the first lumen **512d** of catheter sheath **512** and that projection **528** (not called out) is received in receiver **529** (not called out in these figures).

In various embodiments, various components or devices associated with housing **520** have respective positionings depicted in FIG. **5S-1** that correspond to an expanded configuration of manipulable portion **502** having a state that is the same or similar to the first fanned configuration **536** exemplified in FIG. **5L-1**. It is understood that other configurations or configuration states of manipulable portion **502** may correspond to the configuration of housing **520** in FIG. **5S-1** in other embodiments. Cover **520a** is shown in a first position **570a** in FIG. **5S-1**. In various embodiments, first position **570a** is also referred to as a closed position that may restrict user access to some other portion of housing **520** or some particular device or devices accommodated by housing **520**. In various embodiments, user access to various actuators in an actuator set is restricted when cover **520a** is in the first position **570a**. For example, user access to a first actuator set (e.g., first actuator set **540**) that includes first particular actuator **540a** and second particular actuator **540b** (or at least part of each of first particular actuator **540a** and second particular actuator **540b**) is restricted when cover **520a** is in the first position **570a** in some embodiments. In various embodiments, cover **520a** is selectively moveable between first position **570a** and a second position **570b** (shown in FIG. **5S-2**) located to allow or permit user access to first particular actuator **540a** and second particular actuator **540b**. In some embodiments, second position **570b** is also referred to as an open position. In some embodiments, cover **520a** forms part of an interlock whose operation prevents an operation of another device. For example, when the cover **520a** is moved into the first position **570a** from another position, access to, or operation of, first particular actuator **540a** and second particular actuator **540b** is prevented.

In various embodiments cover **520a** forms part of, or is physically or operatively coupled to, an actuator that is selectively moveable between at least two different activation positions. In some embodiments, cover **520a** forms part of, or is physically coupled to, an actuator that is selectively moveable between at least two activation positions to vary a size, a shape, or both a size and a shape of manipulable portion **502** or an expanded configuration of the manipulable portion **502**. For example, in some embodiments, cover **520a** forms a part of an actuator set comprising an actuator **572** configured to vary a size, shape, or both size and shape of an expanded configuration of manipulable portion **502** from the first fanned configuration **536** exemplified in FIGS. **5L-1**, **5L-2** to a second fanned configuration **537** (also referred to as a bifurcated doming configuration) exemplified in FIGS. **5M-1**, **5M-2** when a movement of cover **520a** causes actuator **572** (e.g., at least first fanning slider **572a** shown in FIG. **5R-1**) to move from a first activation position (e.g., position **571a** shown in FIG. **5S-1**) into a second activation position (e.g., position **571b** shown in FIG. **5S-2**). In this regard, the actuator **572** (also referred to herein as a third particular actuator in some embodiments) is selectively moveable into a respective activation position (e.g., **571b**) to fan at least some of the plurality of elongate members **504**

102

with respect to one another to create a fanned arrangement radiating from a location between the proximal portion **508a** and the distal portion **508b** of the manipulable portion **502** when the manipulable portion **502** is in the expanded configuration. It is understood that although first position **570a** and position **571a** are shown as being the same position in FIG. **5S-1** and second position **570b** and position **571b** are shown as being the same position in FIG. **5S-2**, (a) first position **570a** and the first activation position may be different, (b) second position **570b** and the second activation position may be different, or both (a) and (b) in other embodiments. In FIG. **5M-1**, at least some of the elongate members **504** are additionally fanned by actuator **572** to reconfigure an expanded configuration of manipulable portion **502** from the first fanned configuration or state **536** to the second fanned configuration or state **537**. In various embodiments, at least some of the elongate members **504** are additionally fanned (e.g., fanned in addition to the autonomous fanning described above in this disclosure) to more fully or more evenly increase a circumferential distribution of the elongate members **504**. For example, FIGS. **5L-2** and **5M-2** respectively show top plan views of the expanded manipulable portion **502** in the first fanned configuration **536** and the second fanned configuration **537**. As compared with FIG. **5L-2**, various portions of the elongate members **504** are more fully or more completely circumferentially distributed in FIG. **5M-2**.

A fuller or more complete circumferential distribution of the elongate members **504** may be motivated by various reasons. For example, such a distribution may be better suited for distributing an array of transducers (e.g., transducers **506**) over a greater interior surface region of bodily cavity into which manipulable portion **502** is introduced. In various embodiments associated with FIG. **5M-1**, the proximal portion **508a** of manipulable portion **502** forms a first domed shape **508a-1**, and the distal portion **508b** of manipulable portion **502** forms a second domed shape **508b-1**, when the manipulable portion is in a deployed configuration.

Different actuators may be implemented as actuator **572** in various embodiments. In some embodiments associated with FIG. **5M-1**, actuator **572** may work in a same or similar fashion to the separator **2852** described in co-assigned International Application No.: PCT/US2012/022061, which is incorporated herein by reference. For example, actuator **572** may include a mechanism that converts an input movement (e.g., an input movement of cover **520a**) into an output movement of various control elements **573** (shown in FIG. **5M-1**) in a manner suitable for additionally fanning of the elongate members **504**. In FIG. **5M-1**, each control element **573** includes a control cable **573b** received in a lumen of sleeve **573a** (e.g., the same or similar to flexible lines **2853** and tubular members **2854** in co-assigned International Application No.: PCT/US2012/022061, which is incorporated herein by reference). In FIG. **5M-1** sleeves **573a** are physically coupled (or, in some embodiments, fixedly coupled) to surface **518b** of an elongate member **504** (e.g., an elongate member **504** positioned at the bottom of the stacked arrangement), each of the sleeves **573a** sized to terminate at a respective location along a length of the elongate member **504**. In various embodiments, each of at least some of the sleeves **573a** is sized to terminate at different longitudinal locations along the length of elongate member **504**. Each of the termination locations is a selected position where exiting portions of the respective cables **573b** may be positioned at a desired location along the length of the elongate member **504**. Each termination location may be chosen to advantageously allow the respective exiting cable

103

573b to apply force with sufficient mechanical advantage to move the expanded configuration of the manipulable portion 502 between the two fanned states. From each termination location, the respective exiting cable 573b is physically coupled to an adjacent elongate member 504. In FIG. 5M-1 two sets of exiting cables 573b couple the two portions 508a and 508b to additionally fan the elongate members (i.e., one set of the exiting cables 573b being on a far side of manipulable portion 502 depicted in FIG. 5M-1 and thereby not visible). In various embodiments, movement of the actuator 572 from the first activation position (e.g., position 571a) into the second activation position (e.g., position 571b) (for example, as a consequence of movement of cover 520a) increases tension levels in various cables 573b sufficiently to draw the associated coupled adjacent elongate members 504 toward each other to move the manipulable portion 502 from the first fanned configuration or state 536 into the second fanned configuration or state 537. For example, with reference to FIGS. 5R-1 and 5R-2, actuator 572 includes a first fanning slider 572a moveable along guide 542e and a pair of second fanning sliders 572b, 572c, each moveable along guide 542f. In various embodiments, various ones of the cables 573b (not shown in FIGS. 5R-1, 5R-2 for clarity) are physically coupled to respective ones of the second fanning sliders 572b, 572c. First fanning slider 572a is physically coupled (for example via passageway or channel between guides 542e and 542f) to at least one of the second fanning sliders 572b, 572c to move the connected at least one of the second fanning sliders 572b, 572c to increase tension levels in the various ones of the cables 573b when first fanning slider 572a is moved, for example, between the first activation position (e.g., position 571a) and the second activation position (e.g., position 571b) (e.g., as a consequence of movement of cover 520a). In some embodiments, various devices may be employed to delay a movement of one of the second fanning sliders 572b, 572c until another of the second fanning sliders 572b, 572c has moved by a desired amount or has moved to a desired location under the influence of a movement of first sleeve slider 572a. Such delays may be used to move the expanded configuration of the manipulable portion 502 between the two fanned states in a series of staged movements. In some embodiments, a movement of one of the second fanning sliders 572b, 572c may stop before another of the second fanning sliders 572b, 572c does. In various embodiments, the respective sleeve 573a associated with each respective cable 573b maintains the respective cable 513b in a position suitable for applying the fanning force in a suitable direction during the tensioning of the cable 573b (e.g., which may be or may not be similar to a Bowden cable). Various ones of the elongate members 504 may be additionally physically coupled together by coupling members (similar to or the same as coupling members 2858 in co-assigned International Application No.: PCT/US2012/022061, which is incorporated herein by reference). In various example embodiments, each coupling member may allow movement of one of the elongate members 504 coupled by the coupling member to also cause movement of another of the elongate members 504 coupled by the coupling member. In some example embodiments, the coupling members are arranged to restrict or limit an amount of movement that an elongate member 504 undergoes as the portion of the device is moved into the second fanned configuration 537. For clarity, control element 513 is not shown in FIGS. 5M-1 and 5M-2. For clarity, the various control elements 573 are only shown in FIG. 5M-1. In some embodiments, actuator 572 forms part of the first actuator set 540.

104

In some embodiments, a locking device is selectively operable in a locked configuration which restricts cover 520a from moving at least in a direction away from the second position 570b (or, in some embodiments in which cover 520a forms part of actuator 572, from the second activation position 571b) and an unlocked configuration which permits cover 520a to move at least in the direction away from the second position 570b (or from the second activation position 571b). For example, in some embodiments, biasing member 520c (i.e., FIG. 5R-1) is arranged to provide a force on cover 520a that biases cover 520a downward or toward an upper surface of housing 520. When the cover 520a is moved from the first position 570a (i.e., FIG. 5S-1) to the second position 570b (i.e., FIG. 5S-2) (or from first activation position 571a to second activation position 571b), biasing member 520c forces the cover 520a downward to entrap a portion of the cover 520a against stop elements 520d (i.e., shown in FIG. 5S-1) and thereby locking cover 520a at second position 570b. In some embodiments, cover 520a is released from its locked state when a pulling force (for example as applied by a user) is applied upwardly to the cover 520a against the biasing action of biasing member 520c and out of unlocked engagement with stop elements 520d. When the cover 520a is released from its locked state, movement away from second position 570b or second activation position 571b is permitted. In some embodiments, the ability to lock actuator 572 (for example via cover 520a) advantageously enables the second fanned configuration 537 to be maintained.

The expanded configuration may be moved into other, different states in some embodiments. It is noted in various embodiments that, in any of the various states of the expanded configuration, the manipulable portion 502 may be sized too large for delivery through the lumen 512d of catheter sheath 512 (e.g., during percutaneous delivery of manipulable portion 502) or at least a part of the manipulable portion 502 may be too large to fit in the lumen 512d of catheter sheath 512. As compared between FIGS. 5S-2 and 5S-3, first particular actuator 540a is moved from a first activation position (e.g., position 574a shown in FIG. 5S-2) into a second activation position 574b shown in FIG. 5S-3) to vary a size, shape, or both size and shape of the expanded configuration of manipulable portion 502 from the second fanned configuration 537 exemplified in FIGS. 5M-1, 5M-2 into an enlarged expanded configuration 538 exemplified in FIG. 5N. In various embodiments, movement into the enlarged expanded configuration 538 may be caused by an increase in a radial spacing between various elongate members 504 in the circumferential distribution of the elongate members 504 associated with the second fanned configuration 537 (e.g., an increase in a radial distance of various ones of the elongate members 504 from a central axis of the circumferential distribution). In various embodiments, movement into the enlarged expanded configuration 538 may be caused by an increase in an overall size or dimension of the manipulable portion 502. In various embodiments, movement into the enlarged expanded configuration 538 may be caused by an increase in a distance between respective apexes of the two domed shaped portions 508a-1 and 508b-1. Changing the expanded configuration of the manipulable portion 502 into the enlarged expanded configuration 538 may be motivated for various reasons. For example, manipulable portion 502 may be manipulated into the enlarged expanded configuration 538 to create a conformance, or increase a level of conformance with a tissue surface within a bodily cavity into which the manipulable portion 502 is deployed. In some example embodiments,

105

manipulable portion 502 may be further manipulated into the enlarged expanded configuration 538 to position various transducer elements 506 in closer proximity to an interior tissue surface within a bodily cavity.

In various example embodiments, first particular actuator 540a is moved from its respective first activation position 574a into its second activation position 574b to manipulate cable 513b to reduce a length of the portion 514 (not called out in FIG. 5N) of cable 513b that extends outwardly from sleeve 513a to manipulate the distal end of manipulable portion 502 into closer proximity to the sleeve 513a. This movement of cable 513b draws the domed distal portion 508b in closer proximity to sleeve 513a and increases or enlarges an overall size of the manipulable portion 502. With reference to FIG. 7, movement of the expanded configuration of manipulable portion 502 into the enlarged expanded configuration 538 accompanies a movement of forming slider 561 proximally along guide 542a to take up cable 513b. In FIG. 5S-3, handle 543a of first particular actuator 540a has been rotated (e.g., by a user manipulation) in rotational direction 576 to cause a locking device (e.g., locking device of FIG. 10) of first particular actuator 540a to move from an unlocked configuration to a locked configuration suitable for maintaining the first particular actuator 540a in the second activation position 574b. In this regard, first Bowden cable 552 (i.e., which includes sleeve 552a and cable 513b) is operable in various different configurations. For example, in various embodiments, at least one actuator is physically or operatively coupled to the first Bowden cable 552 to (a) move the sleeve 552a independently or separately from the cable 513b to cause the sleeve 552a to slide over the cable 513b during a first manipulation of the manipulable portion 502 to change, a size, a shape, or both thereof (e.g., as described above with respect to the manipulation of manipulable portion 502 in FIGS. 5H, 5I and 5J), and (b) move the cable 513b independently or separately from the sleeve 552a to cause the cable 513b to slide through the lumen of the sleeve 552a during a second manipulation of the manipulable portion 502 to change a size, a shape, or both thereof (e.g., as described above with respect to the manipulable portion 502 in FIG. 5N).

In some embodiments, the expanded configuration of manipulable portion 502 is manipulated into other states. For example, as compared between FIGS. 5S-3 and 5S-4, first particular actuator 540a is unlocked and moved from a first activation position (e.g., position 574b shown in FIG. 5S-3 and previously referred above in this disclosure as a second activation position associated with a transition into the enlarged expanded configuration 538) into a second activation position (e.g., position 574c shown in FIG. 5S-4) to vary a size, shape, or both size and shape of the expanded configuration of manipulable portion 502 from the enlarged expanded configuration 538 exemplified in FIG. 5N into a flattened expanded configuration 539 exemplified in FIG. 5O. As shown in FIG. 5O, at least some of the elongate members 504 are further manipulated (e.g., at least by the first particular actuator 540a in FIG. 7, among others) to distort at least one of the domed shapes 508a-1, 508b-1 of a respective one of the proximal and the distal portion 508a, 508b of manipulable portion 502. In this regard, in some embodiments, the first particular actuator 540a is selectively moveable into a respective activation position (e.g., 574b or 574c) to (a) act on the proximal portion 508a of the manipulable portion 502 when the manipulable portion 502 is in the expanded configuration to distort the first domed shape 508a-1, (b) act on the distal portion 508b of the manipulable portion 502 when the manipulable portion 502

106

is in the expanded configuration to distort the second domed shape 508b-1, or both (a) and (b). In some embodiments, manipulable portion 502 is manipulated to have a more oblate shape. Changing the expanded configuration of the manipulable portion 502 into the flattened expanded configuration 539 may be motivated for various reasons. For example, manipulable portion 502 may be manipulated into the flattened expanded configuration 539 to better fit within a particular shape of a bodily cavity into which the manipulable portion 502 is deployed.

In FIG. 5O, a control element 578 is provided to convert an input movement (e.g., an input movement of first particular actuator 540a) into an output movement suitable for manipulating the expanded configuration of manipulable portion 502 into the flattened expanded configuration 539. In FIG. 5O, the control element 578 includes a control cable 578b received in a lumen of sleeve 578a that is physically coupled to surface 518b of an elongate member 504. In various embodiments, sleeve 578a is sized to extend generally circumferentially along the manipulable portion 502 and terminate at a location proximate the distal ends 505 of the elongate members 504. From this termination location, the exiting cable 578b extends outwardly from the sleeve 578a and is physically coupled to the manipulable portion 502 at a location proximate a crossing location of various ones of the elongate members 504. In various embodiments, a first particular actuator 540a causes an amount of length of the cable 578b exiting sleeve 578a to decrease as the first particular actuator 540a is moved between the activation positions 574b and 574c. A reduction in the amount of length of the exiting portion of the cable 578b in turn flexes the expanded configuration of the manipulable portion 502 into the flattened expanded configuration 539. As noted above in this disclosure, first particular actuator 540a may be physically or operatively coupled to cable 513b in various embodiments. In some of these various embodiments, first particular actuator 540a includes a mechanism configured to decouple from or cease manipulating control element 513b as the first particular actuator 540a is moved between activation positions 574b and 574c. For clarity, control element 513 is not shown in FIG. 5O. For clarity, control element 578 is only shown in FIG. 5O.

In FIG. 5S-4, handle 543a of first particular actuator 540a has been rotated (e.g., by a user manipulation) in rotational direction 576 to cause a locking device (e.g., locking device of FIG. 10) of first particular actuator 540a to move from an unlocked configuration to a locked configuration suitable for maintaining the first particular actuator 540a in the second activation position 574c. It is noted that, in some embodiments, the first particular actuator 540a may be moved from some other first activation position (for example position 574a in FIG. 5S-2) as it is moved directly or continuously toward or to the second activation position (e.g., position 574c) to move into the flattened expanded configuration 539 without pausing or stopping at position 574b. That is, pausing or stopping at the enlarged expanded configuration 538 need not be required in some embodiments during a transition toward or to the flattened expanded configuration 539.

In some embodiments, the expanded configuration of manipulable portion 502 may be manipulated into yet other states. For example, as compared between FIGS. 5S-3 and 5S-5, second particular actuator 540b may be moved from a first activation position (e.g., position 575a shown in FIG. 5S-3) into a second activation position (e.g., position 575b shown in FIG. 5S-5) to vary a size, shape, or both size and shape of the expanded configuration of manipulable portion

107

502 from the enlarged expanded configuration **538** exemplified in FIG. **5N** into an open clam shell configuration **544a** exemplified in FIG. **5P**. To arrive at the open clam shell configuration **544a**, in some embodiments, the distal portion **508b** of the manipulable portion **502** is pivoted, by selective movement of the second particular actuator **540b** into a respective activation position (e.g., **575b**), away from the proximal portion **508a** of manipulable portion **502** to orient the respective domed shapes **508b-1**, **508a-1** apart from one another.

For another example, as compared between FIGS. **5S-3** and **5S-6**, second particular actuator **540b** may additionally or alternatively be moved from a first activation position (e.g., position **575a** shown in FIG. **5S-3**) into a second activation position (e.g., position **575c** shown in FIG. **5S-6**) to vary a size, shape, or both size and shape of the expanded configuration of manipulable portion **502** from the enlarged expanded configuration **538** exemplified in FIG. **5N** into a closed clam shell configuration **544b** exemplified in FIG. **5Q** as by way of another example. To arrive at the closed clam shell configuration **544b**, the distal portion **508b** of the manipulable portion **502** is pivoted by selective movement of the second particular actuator **540b** into a respective activation position (e.g., **575c**) toward or into the proximal portion **508a** of manipulable portion **502**, which may, in some embodiments, enclose the respective domed shapes **508b-1**, **508a-1** at least partially within one another. In this regard, in some embodiments, the second particular actuator **540b** is selectively moveable into a respective activation position (e.g., **575b** or **575c**) to pivot the proximal portion **508a** and the distal portion **508b** of the manipulable portion **502** with respect to one another when the manipulable portion **502** is in the expanded or deployed configuration.

Each of the open and closed clam shell configurations may be motivated for different reasons. For example, the open clam shell configuration **544a** may be desired to increase an overall size of the manipulable portion **502**, while the closed clam shell configuration **544b** may be desired to decrease an overall size of the manipulable portion **502**, thereby allowing the manipulable portion **502** to be accommodated in a various bodily cavities having a range of different sizes.

In various embodiments, a portion of control element **513** is manipulated by second particular actuator **540b** to selectively transition the expanded configuration of the manipulable portion **502** into at least one of the open or closed clam shell configurations **544a**, **544b**. For example, with reference to FIG. **7**, movement of the expanded configuration of manipulable portion **502** into the closed clam shell configuration **544b** of FIG. **5Q** accompanies a movement of the second particular actuator **540b**'s sleeve slider **548a** distally along guide **542b** to manipulate control element **513** to cause an amount of length of at least the sleeve **513a** extending outwardly from the distal end **510b** of shaft **510** to increase and apply a "push" force on the distal portion **508b** to move at least toward the proximal portion **508a** in various embodiments. In some embodiments, an amount of length of the cable **513b** extending outwardly from the distal end **510b** of shaft **510** also increases as sleeve slider **548a** is moved distally. In some embodiments, both sleeve **513a** and cable **513b** are moved concurrently. In some embodiments, both sleeve **513a** and a portion of cable **513b** within the lumen of sleeve **513a** are moved with little or no relative movement therebetween.

In some embodiments, movement of the expanded configuration of manipulable portion **502** into the open clam shell configuration **544a** of FIG. **5P** accompanies a move-

108

ment of sleeve slider **548a** proximally along guide **542b** to manipulate control element **513** to cause an amount of length of at least the cable **513b** extending outwardly from the distal end **510b** of shaft **510** to decrease and apply a "pull" force on the distal portion **508b** to move away from the proximal portion **508a**. In various embodiments, the extending portion of cable **513b** is retracted into a notch or channel **547** positioned to allow for greater separation between the distal and proximal portions **508a** and **508b** in the open clam shell configuration. In some embodiments, sleeve **513a** is additionally retracted proximally as sleeve slider **548a** is moved proximally. In some embodiments, both sleeve **513a** and cable **513b** are moved concurrently. In some embodiments, both sleeve **513a** and a portion of cable **513b** within the lumen of sleeve **513a** are moved with little or no relative movement therebetween. Channel **547** is shown only in FIGS. **5P** and **5Q** for clarity.

In each of FIGS. **5S-5** and **5S-6**, handle **543b** of second particular actuator **540b** has been rotated (e.g., by a user manipulation) in rotational direction **577** to cause a locking device (e.g., locking device of FIG. **10**) of second particular actuator **540b** to move from an unlocked configuration to a locked configuration suitable for maintaining the second particular actuator **540b** in respective ones of the second activation positions **575b** and **575c**.

As can be seen from FIG. **5S**, in some embodiments, each of the respective actuators (e.g., **540a**, **540b**) in the first actuator set **540** comprises a handle (e.g., **543a**, **543b**) operatively coupled to a respective locking device (e.g., locking device of FIG. **10**) to selectively move the respective locking device between an unlocked configuration and a locked configuration.

It is understood that in various embodiments, at least two of the actuators in the actuator set may be moved from their respective first activation positions into their second respective second activation positions to collectively change the size, the shape, or both a size and a shape of an expanded configuration of the manipulable portion **502** into a particular state. For example, both the first and second particular actuators **540a** and **540b** may be moved into various associated second activation positions to collectively change a size, a shape, or both a size and a shape of an expanded configuration of the manipulable portion **502** into combinations of the various states described above in this disclosure. In some embodiments, a user may chose the locations of the second activation positions and they need not occur at the end-of-travel. In some embodiments, the particular state includes, at least in part, a combination of the various states described above in this disclosure. The manipulable portion **502** has a size too large to be delivered percutaneously to the bodily cavity when the manipulable portion **502** is in the particular state, in some embodiments.

Multiple actuator sets may be associated with catheter system **500**. In some embodiments, a first actuator set includes one or more actuators at least operatively coupled to manipulable portion **502** to change or vary a size, a shape, or both a size and a shape of an expanded configuration of the manipulable portion **502**. In some embodiments, a first actuator set includes two or more actuators at least operatively coupled to the manipulable portion **502**, each of the actuators in the first actuator set independently or separately moveable from the other actuators in the first actuator set from a respective first activation position into a respective second activation position to independently change a size, a shape, or both a size and a shape of an expanded configuration of the manipulable portion **502**. As described above in this disclosure, at least two actuators in the first actuator set

540 may be moveable from their respective first activation positions into their respective second activation positions to collectively change the size, the shape, or both a size and a shape of the expanded configuration of the manipulable portion **502** into a particular state. In this regard, in some embodiments, the manipulable portion **502** is in the expanded configuration when the at least two actuators in the first actuator set **540** are in their respective first activation positions and when the at least two actuators in the first actuator set **540** are in their respective second activation positions. In some embodiments, the manipulable portion **502** has a size too large to be delivered percutaneously to the bodily cavity when the manipulable portion **502** is in the particular state.

For example, FIGS. **5W-1**, **5W-2**, **5W-3**, and **5W-4** (collectively, FIG. **5W**) each respectively show plan and elevation views of a portion of catheter system **500** according to some embodiments. In particular, FIG. **5W-1** shows a positioning of each of various actuators in first actuator set **540** including a positioning of first particular actuator **540a** in respective second activation position **574c** and a positioning of second particular actuator **540b** in respective second activation position **575b**. Cover **520a** has been moved from its first position **570a** (e.g., called out in FIGS. **5S-1** and **5W-4** but not shown in FIG. **5W-1**) to its second position **570b** to permit user access to actuators **540a** and **540b** so as to allow movement of actuators **540a** and **540b** into their respective second activation positions **574c**, **575b** from their respective first activation positions **574a**, **575a** (e.g., called out in FIG. **5S-2** but not called out in FIG. **5W-1**). Additionally, third particular actuator **572** has been moved (e.g., via manipulation of cover **520a**) into its respective second activation position **571b** from its first activation position **571a** (e.g., called out in FIGS. **5S-1** and **5W-4**, but not called out in FIG. **5W-1**). (Cover **520a** has been sectioned in the respective plan view of each of FIGS. **5W-1**, **5W-1**, **5W-3** and **5W-4** for clarity of view of various features associated with cover **520a**.) Accordingly, the positioning of these actuators into their respective second activation positions collectively changes the size, the shape, or both a size and a shape of the expanded configuration of the manipulable portion **502** into a particular state.

In some embodiments, the particular state of the expanded configuration corresponding to the various actuator positions shown in FIG. **5W-1** is collectively a combination of the flattened expanded configuration exemplified in FIG. **5O** and the open clam shell configuration **544a** exemplified in FIG. **5P**. It is understood that other combinations of expanded configurations are provided in other embodiments. In various embodiments, manipulable portion **502** has a size too large for percutaneous delivery or a size too large to fit in the lumen **512d** of catheter sheath **512** when the expanded configuration of the manipulable portion is moved into a particular state in response to the positioning of the various actuators into their respective second activation positions.

In FIG. **5W-1**, handle **543a** of first particular actuator **540a** has been rotated (e.g., by a user manipulation) in rotational direction (e.g., rotational direction **576**, not called out in FIG. **5W-1**) to cause a locking device (e.g., locking device of FIG. **10**) of first particular actuator **540a** to move from an unlocked configuration to a locked configuration suitable for maintaining the first particular actuator **540a** in its second activation position **574c**. In FIG. **5W-1**, handle **543b** of second particular actuator **540b** has been rotated (e.g., by a user manipulation) in a rotational direction (e.g., rotational direction **577**, not called out in FIG. **5W-1**) to cause a locking device (e.g., locking device of FIG. **10**) of

second particular actuator **540b** to move from an unlocked configuration to a locked configuration suitable for maintaining the second particular actuator **540b** in its second activation position **575b**. In various embodiments, third particular actuator **572** is also locked in its respective second activation position **572** (for example as described above in this disclosure).

In some embodiments, a second actuator set is employed. The second actuator set may include a particular actuator moveable between two activation positions to cause at least two actuators in the first actuator set that are positioned in their respective second activation positions to move away from their respective second activation positions to cause the collectively changed size, the collectively changed shape, or both the collectively changed size and shape of the expanded configuration of the manipulable portion **502** to move away from a particular state corresponding to the positioning of the at least two actuators in the first actuator set in their respective second activation positions. For example, in various embodiments, actuator **572** is a particular actuator in a second actuator set **541** that is moveable between two activation positions to cause the at least two actuators (e.g., actuators **540a**, **540b**) in the first actuator set **540** that are positioned in their respective second activation positions (e.g., second activation positions **574c**, **575b**) to move away from their respective second activation positions to cause the collectively changed size, the collectively changed shape, or both the collectively changed size and shape of the expanded configuration of the manipulable portion **502** to move away from the particular state corresponding to the positioning of the at least two actuators in their respective second activation positions.

In some embodiments, first actuator set **540** does not include any actuator in the second actuator set **541**. In some embodiments, the at least two actuators (e.g., actuators **540a**, **540b**) in the first actuator set **540** do not include any actuator (e.g., actuator **572**) in the second actuator set **541**. However, a particular actuator (e.g., actuator **572**) in the second actuator set **541**, in some embodiments, may also form part of the first actuator set **540**. For example, recall that the first actuator set **540** may be defined to include one or more actuators (e.g., actuators **540a**, **540b**) at least operatively coupled to manipulable portion **502** to change or vary a size, a shape, or both a size and a shape of an expanded configuration of the manipulable portion **502**. Also recall that the second actuator set **541** may be defined to include a particular actuator (e.g., actuator **572**) moveable between two activation positions to cause at least two actuators (e.g., actuators **540a**, **540b**) in the first actuator set that are positioned in their respective second activation positions to move away from their respective second activation positions to cause the collectively changed size, the collectively changed shape, or both the collectively changed size and shape of the expanded configuration of the manipulable portion **502** to move away from a particular state corresponding to the positioning of the at least two actuators in the first actuator set in their respective second activation positions. In this case, in some embodiments, the particular actuator (e.g., actuator **572**) may meet the definition or perform the functionalities of both the first actuator set **540** and the second actuator set **541**. In such a case, the particular actuator (e.g., actuator **572**) may be considered part of both the first actuator set **540** and the second actuator set **541**.

For instance, if actuator **540a** is a first particular actuator, actuator **540b** is a second particular actuator, and actuator **572** is a third particular actuator **572**, the third particular actuator **572**: (a) may cause, according to a definition or

111

functionality of the second actuator set **541**, according to some embodiments, the first and second particular actuators **540a**, **540b** to move away from their respective second activation positions (e.g., respective ones of second activation positions **574c**, **575b**) when actuator **572** moves between its respective activation positions **571a**, **571b**, and (b) may, according to a definition or functionality of the first actuator set **540**, according to some embodiments, be further independently or separately moveable from the other actuators in the first actuator set **540** from a respective first activation position **571a** into a respective second activation position **571b** to independently change a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion **502**. Regarding (b), for example, the third particular actuator **572** may cause the expanded configuration of the manipulable portion **502** to change between a first fanned configuration **536** exemplified in FIGS. **5L-1** and **5L-2** and a second fanned configuration **537** exemplified in FIGS. **5M-1** and **5M-2**. Accordingly, the third particular actuator **572**, in some embodiments, may be considered part of both the first actuator set **540** and the second actuator set **541**. However, whether or not the first actuator set **540** includes an actuator in the second actuator set **541** depends on the particular embodiment employed.

FIG. **5W** show a movement of third particular actuator **572** at four successive points in time during a movement of third particular actuator **572** between two activation positions. In these illustrated embodiments, third particular actuator **572** is moved (e.g., via manipulation of cover **520a**) from second activation position **571b** (i.e., called out in FIG. **5W-1**) toward or to first activation position **571a** (i.e., called out in FIG. **5W-4**). In some embodiments, a locking device associated with third particular actuator **572** (e.g., the locking device associated with cover **520a** described above in this disclosure) is unlocked before the commencement of this movement. In various embodiments, the movement of third particular actuator **572** between the two activation positions **571a** and **571b**, and, in particular, from the second activation position **571b** toward or to first activation position **571a**, causes each of the first particular actuator **540a** and the second particular actuator **540b** to move away from their respective activation positions **574c**, **575b** as shown in FIGS. **5W-2**, **5W-3** and **5W-4**. For example, in some embodiments, third particular actuator **572** includes at least a first actuator override **520e** and a second actuator override **520f**. In various embodiments, first actuator override **520e** is configured to override an operative state associated with first particular actuator **540a**. In various embodiments, second actuator override **520e** is configured to override an operative state associated with second particular actuator **540b**. In some embodiments, first actuator override **520e** is configured to override an operative positioning of first particular actuator **540a** at its respective second activation position (e.g., second activation position **574c**) and cause it to move away from its respective second activation position. In some embodiments, second actuator override **520f** is configured to override an operative positioning of second particular actuator **540b** at its respective second activation position (e.g., second activation position **575b**) and cause it to move away from its respective second activation position. In some embodiments, the first actuator override **520e**, the second actuator override **520f**, or each of the first and the second actuator overrides **520e**, **520f** is operatively coupled (for example via a linkage or other force transmission member or mechanism) to a respective one of first particular actuator **540a** and second particular actuator **540b** to cause movement thereof. In some embodiments, the first actuator over-

112

ride **520e**, the second actuator override **520f**, or each of the first and the second actuator overrides **520e**, **520f** is configured to be selectively brought into engagement or disengagement with a respective one of first particular actuator **540a** and second particular actuator **540b**. For example, in some embodiments, each of the first and the second actuator overrides **520e**, **520f** may include a slot, cavity, tunnel, or other receiver or engagement mechanism that includes one or more engagement surfaces that may be selectively brought into contact or engagement with a respective one of the first particular actuator **540a** and second particular actuator **540b**.

In some embodiments associated with FIG. **5W**, each of the first and second overrides **520e**, **520f** is provided by, or forms part of third particular actuator **572**. In some embodiments associated with FIG. **5W**, each of the first and second overrides **520e**, **520f** of third particular actuator **572** is provided by, or forms part of the cover **520a**, which may in turn, form part of third particular actuator **572** in some embodiments. In some embodiments, first actuator override **520e** includes various engagement surfaces (e.g., engagement surfaces **520e-1** and **520e-2**) configured to engage and subsequently manipulate a portion of first particular actuator **540a**. In some embodiments, second actuator override **520f** includes various engagement surfaces (e.g., engagement surfaces **520f-1** and **520f-2**) configured to engage and subsequently manipulate a portion of second particular actuator **540b**. It is noted that although surfaces **520e-1** and **520e-2** are called out separately, they may form part of a single or uniform surface in some embodiments. It is noted that although surfaces **520f-1** and **520f-2** are called out separately, they may form part of a single or uniform surface in some embodiments.

As third particular actuator **572** is moved from its second activation position **571b** (e.g., FIG. **5W-1**) toward or to its first activation position **571a** (e.g., FIG. **5W-4**), the engagement surface **520e-1** of first actuator override **520e** is brought into contact, or otherwise engages with a portion of first particular actuator **540a** (e.g., FIG. **5W-2**). In some embodiments, the first engagement surface **520e-1** (or other engagement surface of first actuator override **520e**) is brought into contact, or otherwise engages, with handle **543a** of first particular actuator **540a**. In some embodiments, engagement surface **520e** forms part of a cam (e.g., a linear cam) that is arranged to act on a cam follower (e.g., handle **543a**) to move the cam follower in a desired manner. In some embodiments, engagement surface **520e-1** forms part of a cam that is arranged to act on a cam follower (e.g., handle **543a**) to move the cam follower to move a locking device (e.g., locking device of FIG. **10**) of first particular actuator **540a** between a locked and unlocked configuration. For example, in FIG. **5W-2**, handle **543a** is oriented in a manner similar to, or the same as in FIGS. **5S-3**, **5S-4**, **5S-5** and **5S-6** corresponding to a locked configuration or state of a locking device (e.g., locking device of FIG. **10**) that restricts movement (e.g., movement away from second activation position **574c**) of first particular actuator **540a** when handle **543a** is positioned in the locked configuration or state. In some embodiments associated with FIG. **5W-2**, engagement surface **520e-1** contacts handle **543a** to rotate handle **543a** in a direction (e.g., rotational direction **579**) suitable for moving the locking device associated with first particular actuator **540a** from the locked configuration to an unlocked configuration which allows for movement (e.g., movement away from second activation position **574c**) of the first particular actuator **540a**.

113

In various embodiments, once the first actuator **540a** is free to move from its second activation position **574c**, further or subsequent movement of third particular actuator **572** (e.g., by way of manipulation of cover **520a**) causes movement of first particular actuator **540a** away from its second activation position **574c**. In some embodiments, this movement away from the second activation position **574c** occurs when engagement surface **520e-2** of first actuator override **520e** comes into contact, or otherwise engages, a portion of first actuator **540a** (e.g., handle **543a**) to cause movement of first actuator **540a** away from its second activation position **574c**, for example, as shown in FIG. 5W-3.

In some embodiments, the movement of third particular actuator **572** between the two activation positions **571a** and **571b**, (for example, from the second activation position **571b** toward or to first activation position **571a**) causes a first actuator (e.g., first particular actuator **540a**) in the first actuator set **540** to move away from its respective second activation position (e.g., second activation position **574c**) before a second actuator (e.g., second particular actuator **540b**) in the first actuator set **540** is caused to move away from its respective second activation position (e.g., second activation position **575b**) by the third particular actuator **572**. In various embodiments, after the commencement of a movement of the first particular actuator **540a** away from its respective second activation position **574c**, engagement surface **520f-2** contacts, or otherwise engages a portion of second particular actuator **540b** (e.g., handle **543b**) to move second particular actuator **540b** (e.g., in a direction away from second activation position **575b**). For example, in FIG. 5W-3, after the commencement of a movement of the first particular actuator **540a** away from its respective second activation position **574c**, third particular actuator **572** has moved to a position where an engagement surface **520f-1** of second actuator override **520f** contacts, or otherwise engages, a portion of second actuator **540b** (e.g., handle **543b**) to move (for example, by rotating handle **543b** in rotational direction **580**) a locking device (e.g., locking device of FIG. 10) from a locked configuration, which restricts movement of the second particular actuator **540b**, to an unlocked configuration, which permits movement of second particular actuator **540b**.

It is noted, that in some embodiments, the movement of third particular actuator **572** between the two activation positions **571a** and **571b** (e.g., from the second activation position **571b** toward or to first activation position **571a**) may cause a first actuator (e.g., first particular actuator **540a**) in the first actuator set **540** to move away from its respective second activation position at the same time, or at approximately the same time as a second actuator (e.g., second particular actuator **540b**) in the first actuator set **540** is caused to move away from its respective second activation position by the third particular actuator **572**. For example, if first particular actuator **540a** is positioned at second activation position **574b** (i.e., instead of second activation position **574c**) while second particular actuator **540b** is positioned at second activation position **575b** (e.g., in a manner similar to, or the same as that shown in FIG. 5S-5), initial engagement with each of the first and second particular actuators **540a**, **540b** by the third particular actuator **572** may occur at the same time, or at substantially the same time.

In various embodiments, third particular actuator **572** moves from its second activation position **571b** (e.g., FIG. 5W-1) to a location at least proximate its respective first activation position **571a** (e.g., FIG. 5W-4). In various embodiments, movement of the third particular actuator **572**

114

between its respective activations positions **571b**, **571a** causes (a) the first particular actuator **540a** to move from its second activation position (e.g., second activation position **574c**) to a location at least proximate to its first activation position **574a**, (b) the second particular actuator **540b** to move from its second activation position (e.g., second activation position **574b**) to a location at least proximate to its first activation position **575a**, or both (a) and (b) as shown in FIG. 5W-4. In FIG. 5W-4, cover **520a** has been moved from its second position **570b** to its first position **570a**. As described previously in this disclosure, cover **520a** restricts access to the first and second actuators **540a**, **540b** when the cover **520a** is in the first position **570a**.

In various embodiments, when the third particular actuator **572** moves between its two activation positions (for example, from the second activation position **571b** toward or to the first activation position **571a**), each of the first and second particular actuators **540a** and **540b** move away from respective ones of their second activation positions (e.g., second activation positions **574c**, **575b**) to cause a size, a shape, or both a size and a shape of the expanded configuration of manipulable portion **502** to move away from the particular state that the expanded configuration of the manipulable portion **502** assumed when each of the first and second particular actuators **540a** and **540b** were in their respective second activation positions. In some of these embodiments, each of the first and second particular actuators **540a** and **540b** move away from respective ones of their second activation positions (e.g., second activation positions **574c**, **575b**) to cause the particular state of the expanded configuration of the manipulable portion **502** (i.e., when the first and second particular actuators **540a** and **540b** were positioned at respective ones of their second activation positions) to move toward or to the delivery configuration.

In various embodiments, associated with FIG. 5W, movement of the third particular actuator **572** from its second activation position **571b** toward or to its first activation position **571a** causes changes in various states or sub-states of the expanded configuration that were combined to impart the particular collective state or super-state onto the expanded configuration of the manipulable portion **502**. For example, the positioning of each particular actuator (e.g., each actuator **540a**, **540b**, **572**) imparts its own sub-state onto the configuration of the manipulable portion **502**. For example, positioning of the actuator **540b** into its second activation position **575b** causes an open-clam shell sub-state effect on the expanded configuration of the manipulable portion **502** as shown, for example, in FIG. 5P, according to some embodiments. Positioning of the actuator **540a** into its second activation position **574c** causes a flattening sub-state effect on the expanded configuration of the manipulable portion **502** as shown, for example, in FIG. 5O, according to some embodiments. Positioning of the actuator **572** into its second activation position **571b** causes a fanning sub-state effect on the expanded configuration of the manipulable portion **502**, according to some embodiments. Accordingly, the combination of at least some of these individual sub-states is a collective state or super-state of the configuration of the manipulable portion **502**. For instance, positioning of the actuator **540b** into its second activation position **575b**, positioning of the actuator **540a** into its second activation position **574c**, and positioning of the actuator **572** into its second activation position **571b** cause a collective of super-state of the expanded configuration of the manipulable portion **502** that would appear like a combination of FIGS. 5O and 5P.

115

Accordingly, in various embodiments associated with FIG. 5W, changes in these collective or super-states may include a departure from the combined FIG. 5O-5P state when third particular actuator 572 moves the first and second particular actuators 540a and 540b away from their respective second activation positions 574c, 575b. For another example, in various embodiments associated with FIG. 5W, changes in these collective or super-states may include a departure from the second fanned configuration 537 (e.g., exemplified in FIGS. 5M-1, 5M-2) as the third particular actuator 572 moves from the second activation position 571b toward or to the first activation position 571a. In some of these embodiments, departure from these various states may cause the expanded configuration of the manipulable portion 502 to move, at least in part, toward or to the delivery configuration.

In this regard, changes in these collective or super-states may cause the collective or super-state of the configuration of the manipulable portion 502 to be changed from one state to another state. For instance, movement of the third particular actuator 572 from the second activation position 571b toward or to the first activation position 571a may cause the manipulable portion 502 to move from an expanded configuration state toward or to a delivery configuration state.

Accordingly, the expanded configuration of the manipulable portion 502 may undergo various changes as it transitions to a targeted or desired particular state (for example, a state suitable for a particular medical procedure having diagnostic aspects, treatment aspects, or combined diagnostic and treatment aspects) or transitions away from a previously targeted or desired particular state (e.g., during a transition toward or to a delivery configuration which may be motivated for various reasons including a desire to remove the manipulable portion 502 from the body upon which the medical procedure is performed). For example, as described above with respect to FIG. 5S, in some embodiments, each of at least two of the particular actuators (e.g., first particular actuator 540a, second particular actuator 540b) is moveable between its respective first activation position (e.g., a respective one of first activation positions 574a, 575a) and its respective second activation position (e.g., a respective one of second activation positions 574c, 575b) to collectively change a size, a shape or both a size and a shape of the expanded configuration of the manipulable portion 502 from a first particular (e.g., collective or super-) state to a second particular (e.g., collective or super-) state. In some embodiments, each actuator of the at least two actuators (e.g., the first actuator 540a or second actuator 540b) may include a user-accessible portion (e.g., a respective one of handles 543a, 543b) that is slideable relative to a surface of housing 520 by a user to move the actuator between its respective first and second activation positions and cause a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion 502 to be varied. The second particular state may be any of various configurations in various embodiments including the particular state described above in this disclosure in which the expanded configuration includes a combination of the forms shown in FIGS. 5O and 5P. In some embodiments, the first particular state is a preliminary or initial state of the expanded configuration. In other embodiments, the first state results from a transitioning of the expanded configuration from another state (e.g., a third state other than the second state).

In some embodiments, a particular actuator (e.g., actuator 572) in the second actuator set 541 is selectively moveable from one activation position (e.g., first activation position

116

571a) to another activation position (e.g., second activation position 571b) to independently change a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion 502 from a third state to the first state. For example, in some embodiments, manipulation of the third particular actuator 572 from first activation position 571a to second activation position 571b changes an expanded configuration of the manipulable portion 502 from a third state (e.g., first fanned configuration 536) to the first state (e.g., second fanned configuration 537) without engagement or coordinated movement of the actuators 540a, 540b in the first actuator set 540. Subsequent manipulation of various actuators in the first actuator set 540 may further transition the expanded configuration from the first state (e.g., second fanned configuration 537) to the second state (e.g., a combination of FIGS. 5O and 5P) as described above in this disclosure. When the collective or super-state of the configuration of the manipulable portion 502 is changed to the second state or some other state (e.g., the first or third states), it may be said that the collective or super-state to which the manipulable portion 502 is changed is a collectively changed size, a collectively changed shape, or both a collectively changed size and shape of the configuration of the manipulable portion 502.

In various embodiments, when the third particular actuator 572 is moved from its second activation position 571b toward or to its first activation position 571a, various actuators (e.g., first and second particular actuators 540a, 540b) in the first actuator set 540 may move from their respective second activation positions (e.g., second activation position 574c, 575b) to cause a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion 502 to move away from the second state to transition the manipulable portion at least in part toward or to the delivery configuration. In various embodiments, when the third particular actuator 572 is moved from its second activation position 571b toward or to its first activation position 571a, various actuators (e.g., first and second particular actuators 540a, 540b) in the first actuator set 540 may move from their respective second activation positions (e.g., second activation position 574c, 575b) to cause a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion 502 to move away from the second state toward or to the third state (e.g., the first fanned configuration 536).

It is noted, in some embodiments, when the first and second actuators 540a, 540b are moved away from respective ones of their second activation positions (e.g., second activation positions 574c, 575b) to the respective ones of the first activation positions (e.g., first activation positions 574a, 575a), the expanded configuration of the manipulable portion 502 may have a different shape, size, or both size and shape than that possessed by the expanded configuration when the first and second actuators 540a, 540b were positioned at their respective first activation positions during a movement of the first and second actuators 540a, 540b from their respective first activation positions toward or to their respective second activation positions. In other words, the manipulable portion 502 may have a different shape, size, or both size and shape when in the same state (e.g., first activation positions 574a, 575a of first and second actuators 540a, 540b, even when the positioning of the actuator 572 is held constant) at two different times. This situation may happen for various reasons including friction and hysteresis in various portions of the catheter system 500. In some embodiments, the word "state" at least when used in the context of the configuration of the manipulable portion 502

may be understood to be a mode, condition, or characteristic of the configuration of the manipulable portion 502 and is not necessarily limited to an exact positioning, size, or shape of the manipulable portion 502. For example, in some embodiments, a particular collective state of the expanded configuration of the manipulable portion 502 may be a flattened state (e.g., FIG. 50), as opposed to a precise position, size, and shape of the manipulable portion 502 in the flattened state. In some embodiments, a particular collective state of the expanded configuration of the manipulable portion 502 may be defined to include an absence of a particular sub-state, such as an absence of the flattening effects of FIG. 50 (e.g., due to the actuator 540a not being in its second activation position 574c) or an absence of the open clam shell effects of FIG. 5P (e.g., due to the actuator 540b not being in its second activation position 575b).

In various embodiments, a particular actuator (e.g., third particular actuator 572) in the second actuator set 541 is selectively moveable toward or to one particular activation position (e.g., first activation position 571a) while engaging at least two actuators (e.g., first and second particular actuators 540a, 540b) in first actuator set 540, and, consequently, causing the at least two actuators in the first actuator set 540 to move between their respective second and first activation positions (for example as described above with respect to FIG. 5W). In some of these various embodiments, the particular actuator (e.g., third particular actuator 572) in the second actuator set 541 is selectively moveable toward or to another particular activation position (e.g., second activation position 571b) while not engaging various actuators (e.g., first and second particular actuators 540a, 540b or any respective locking device (e.g., FIG. 10) thereof) in first actuator set 540, and while not causing each of the at least two actuators in the first actuator set 540 to move between their respective second and first activation positions (for example as described above with respect to FIGS. 5S-1 and 5S-2). In various embodiments, movement of the particular actuator (e.g., actuator 572) in the second actuator set 541 toward or to the one particular activation position (e.g., first activation position 571a) is in a different direction than movement of the particular actuator in the second actuator set 541 toward or to the another particular activation position (e.g., second activation position 571b).

In various embodiments, catheter system 500 includes an interlock device configured to restrict at least one actuator (e.g., at least first particular actuator 540a, second particular actuator 540b, or both) in the first actuator set 540 from being moved away from a respective first activation position (e.g., a respective one of first activation positions 574a, 575a) until at least a first actuator (e.g., third particular actuator 572) in the second actuator set 541 is moved in response to a user action. For example, the interlock device may be provided at least by a portion (e.g., the cover 520a) of the third particular actuator 572, such that the first particular actuator 540a and the second particular actuator 540b are restricted from moving away from their respective first activation positions 574a, 575a until the cover 520a is moved (e.g., FIGS. 5S-1 to 5S-2). In some embodiments, catheter system 500 includes an interlock device configured to restrict at least one actuator (e.g., at least one of first particular actuator 540a, second particular actuator 540b) in the first actuator set 540 from being moved between the respective first and second activation positions of the at least one actuator in the first actuator set 540 until at least one other actuator in the first actuator set 540 is moved into the respective second activation position of the at least one other actuator in the first actuator set 540. For example, when third

particular actuator 572 forms part of the first actuator set 540, either of first and second particular actuators 540a, 540b is restricted from being moved between its respective first and second activation positions until the third particular actuator 572 is moved away from its first activation position 571a toward or to its second activation position 571b.

The use of an interlock device in various embodiments may be motivated for various reasons. For example, in some embodiments, a particular sequence in the activation of various ones of the actuators is desired. In some embodiments, an interlock device is employed to ensure that one particular actuator is activated to facilitate a subsequent activation of another actuator. For example, in some embodiments, an interlock device (e.g., cover 520a) is used to guide a user to activate actuator 572 to manipulate the expanded configuration of the manipulable portion 502 into the second fanned configuration 537 prior to an activation of any of actuators 540a, 540b. This sequence may be motivated for various reasons including circumventing a condition in which actuator 572, if activated after the activation of one or both of actuators 540a and 540b, could possibly need to apply potentially higher forces (e.g., forces that could damage or render a device of system 500 inoperable) to fan the elongate members 504 of the manipulable portion 502 into the second fanned configuration 537.

In some particular embodiments, cover 520a is configured (e.g., includes one or more suitably positioned engagement surfaces) to engage various ones of the actuators in the first actuation set 540 when the cover 520a is moved in a first direction (e.g., in a direction toward first position 570a) along a path between first and second positions 570a, 570b, but not engage various ones of the actuators in the first actuator set 540 when the cover 520a is moved in a second direction (e.g., in a direction toward second position 570b) along the path between first and second positions 570a, 570b, the second direction being different than the first direction. In some particular embodiments, cover 520a is configured (e.g., includes suitably positioned engagement surfaces) to engage various ones of the actuators in the first actuator set 540 to cause movement thereof when the cover 520a is moved in a first direction (e.g., in a direction toward first position 570a) along a path between first and second positions 570a, 570b, but not engage various ones (or, in some embodiments, any) of the actuators in the first actuation set 540 to cause movement thereof when the cover 520a is moved in a second direction (e.g., in a direction toward second position 570b) along the path between first and second positions 570a, 570b, the second direction being different than the first direction. For example in some embodiments, cover 520a does not engage actuators 540a, 540b and does not move them when the cover 520a moves from first position 570a toward or to second position 570b as described above in this disclosure with respect to various ones of FIG. 5S, but does engage actuators 540a, 540b to cause them to move when the cover 520a moves from second position 570b toward or to first position 570a as described above in this disclosure with respect to various ones of FIG. 5W. Movement of various ones of the actuators in the first actuation set 540 induced by an engagement by the cover 520a may cause, or lead to a change in a size, shape, or both, of an expanded configuration of the manipulable portion 502 away from a particular state. In various embodiments, cover 520a is operatively coupled to manipulable portion 502 to cause the manipulable portion 502 to move, at least partially, from the expanded configuration

119

toward or to the delivery configuration when cover **520a** moves from second position **570b** toward or to first position **570a**.

In various embodiments, catheter system **500** includes an actuator set that includes one or more actuators (e.g., first particular actuator **540a**, second particular actuator **540b** or both of the first and the second particular actuators **540a**, **540b**), each actuator in the actuator set selectively moveable into a respective activation position to cause a size, a shape, or both a size and a shape of the expanded configuration of the manipulable portion **502** to be varied. Cover **520a** is selectively moveable between a first position (e.g., first position **570a**) where user access to at least a respective part (e.g., handle **543a**, **543b**) of each of at least one actuator in the actuator set is restricted and a second position (e.g., second position **570b**) where user access to at least the respective part of each of the at least one actuator in the actuator set is permitted. In some of these various embodiments, when cover **520a** is moved from the second position toward or to the first position, the cover **520a** engages each particular actuator in the actuator set that is positioned in the respective activation position of the particular actuator to move the particular actuator away from the respective activation position of the particular actuator.

In some embodiments, each actuator in the actuator set is selectively moveable into its respective activation position to cause a size, a shape or both a size and a shape of the expanded configuration of the manipulable portion **502** to be varied from an associated respective first (e.g., sub-) state to an associated respective second (e.g., sub-) state. For example, the actuator **540a** is selectively moveable into its respective second activation position **574c** to cause the expanded configuration of the manipulable portion **502** to include the flattened sub-state (e.g., characteristics of FIG. **50**), according to some embodiments. When the cover **520a** is moved from the second position **570b** toward or to the first position **570a**, cover **520a** engages each particular actuator in the actuator set that is positioned in the respective activation position of the particular actuator to move the particular actuator away from its respective activation position to cause, the size, the shape, or both of the expanded configuration of the manipulable portion to move from the respective second state associated with the particular actuator toward or to the respective first state associated with the particular actuator. For example, if movement of the actuator **540a** into its respective second activation position **574c** caused the expanded configuration of the manipulable portion **502** to change from a first state associated with the actuator **540a** (e.g., a state not including the flattened sub-state effects such as shown in FIG. **50**) to a second state associated with the actuator **540a** (e.g., a state including the flattened sub-state effects such as shown in FIG. **50**), the cover **520a** may cause movement of the actuator **540b** away from its respective second activation position **574c** and, consequently, cause the expanded configuration to move from the second state (e.g., a state including the flattened sub-state effects such as shown in FIG. **50**) toward or to the first state (e.g., a state not including the flattened sub-state effects such as shown in FIG. **50**).

In some embodiments, the manipulable portion **502** has a size too large to fit in the lumen **512d** of the catheter sheath **512** or a size too large to be percutaneously delivered to a bodily cavity when the expanded configuration of the manipulable portion **502** is in either of the respective first or second respective states associated with each actuator in the actuator set. In some embodiments, the catheter system **500** includes at least a first actuator (e.g., third particular actuator

120

572) that is selectively moveable into a respective activation position to cause a size, a shape, or both of the expanded configuration of the manipulable portion **502** to be varied, and cover **520a** is operable to cause the first actuator to move (e.g., toward or to its respective activation position) when the cover **520a** is moved between the first position **570a** and the second position **570b** (e.g., from the first position **570a** toward or to the second position **570b**). In some embodiments, the cover **520a** is operable to cause the first actuator (e.g., third particular actuator **572**) to move away from the respective activation position of the first actuator when the cover **520a** is moved from the second position **570b** toward or to the first position **570a**.

In some embodiments, catheter system **500** includes at least a first actuator and a second actuator, each of the first and the second actuators independently or separately moveable with respect to one another into a respective activation position to cause a size, a shape, or both of the expanded configuration of the manipulable portion **502** to be varied from an associated respective first state to an associated respective second state. For example, in some embodiments, a first actuator **540a** is moveable independently or separately with respect to a second actuator **540b** into a respective second activation position **574c** to cause the manipulable portion to be varied from a first state associated with the first actuator **540a** (e.g., a state not including the flattened sub-state effects like FIG. **50**) to a second state associated with the first actuator **540a** (e.g., a state including the flattened sub-state effects like FIG. **50**). Similarly, in some embodiments, the second actuator **540b** is moveable independently or separately with respect to the first actuator **540a** into a respective second activation position **575b** to cause the manipulable portion to be varied from a first state associated with the second actuator **540b** (e.g., a state not including the open-clam-shell sub-state effects like FIG. **5P**) to a second state associated with the second actuator **540b** (e.g., a state including the open-clam-shell sub-state effects like FIG. **5P**).

In at least embodiments like these, cover **520a** is moveable between a first position **570a** where user access to at least a part of the second actuator is restricted and a second position **570b** where user access to at least the part of the second actuator is permitted. In this regard, in some embodiments, cover **520a** is operable to cause the first actuator to move away from the respective activation position of the first actuator when the cover **520a** is moved from the second position **570b** toward or to the first position **570a** to cause the size, the shape, or both of the expanded configuration of the manipulable portion **502** to move from the respective second state associated with the first actuator toward or to the respective first state associated with the first actuator.

For example, in some embodiments, the second actuator is provided by one of the first and second particular actuators **540a** and **540b** (i.e., access to the one of the first and second particular actuators **540a** and **540b** being restricted when cover **520a** is in first position **570a**) and the first actuator is provided by another one of the first and the second particular actuators **540a** and **540b**, the another one of the first and the second particular actuators **540a** and **540b** being caused to move away from the respective activation state of the another one of the first and the second particular actuators **540a** and **540b** when the cover **520a** is moved from the second position **570b** toward or to the first position **570a** to cause the size, the shape, or both of the expanded configuration of the manipulable portion **502** to move from the respective second state associated with the another one of the first and the second particular actuators **540a** and **540b**

121

toward or to the respective first state associated with the another one of the first and the second particular actuators **540a** and **540b**.

In some embodiments, the second actuator is provided by one of the first and the second particular actuators **540a** and **540b**, and the first actuator is provided by the third particular actuator **572**, the third particular actuator **572** being caused (e.g., by engagement) to move away from the respective activation state of the third particular actuator **572** when the cover **520a** is moved from the second position **570b** toward or to the first position **570a** to cause the size, the shape, or both of the expanded configuration of the manipulable portion **502** to move from the respective second state associated with the third particular actuator **572** toward or to the respective first state associated with the third particular actuator **572**. In some embodiments, cover **520a** is physically coupled to and is a user-accessible portion of the first actuator (e.g., actuator **572**) slideable along a surface of the housing **520** to cause the first actuator to move toward or to the respective activation position of the first actuator when the cover **520a** is moved from the first position **570a** to the second position **570b** as described above in this disclosure. In various embodiments, the second actuator (e.g., one of the first and the second particular actuators **540a** and **540b**) includes a user-accessible portion (e.g., handle **543a** or **543b**) slideable relative to a surface of housing **520** by a user to cause the size, the shape or both of the expanded configuration of the manipulable portion **502** to be varied from the respective first state associated with the second actuator to the respective second state associated with the second actuator. The user-accessible portion (e.g., handle **543a** or **543b**) may include a locking device (e.g., locking device of FIG. **10**) as described above, at least a portion of which is rotatable by a user to prevent sliding of at least the user-accessible portion of the second actuator relative to the surface of the housing **520**.

In various embodiments, the manipulable portion **502** has a size too large to fit in the lumen **512d** of catheter sheath **512** or a size too large to be percutaneously delivered to a bodily cavity when the expanded configuration of the manipulable portion **502** is in (a) either of the respective first and second states associated with the first actuator, (b) either of the respective first and second states associated with the second actuator, or both (a) and (b). In various embodiments, the manipulable portion **502** is in the expanded configuration when the second actuator (e.g., one of the first and the second particular actuators **540a** and **540b**) is in its respective activation position. In various embodiments, the manipulable portion **502** is in the expanded configuration when the second actuator (e.g., one of the first and the second particular actuators **540a** and **540b**) is in its respective activation position and when the first actuator (e.g., third particular actuator **572** or another one of the first and the second particular actuators **540a** and **540b**) is in its respective activation position.

It should be noted that many of the various descriptions, above, refer to particular actuators in examples, such as actuators **540a**, **540b**, **572**, etcetera, merely for illustration purposes. In this regard, it should be noted that the present invention is not limited to such particular actuators or their configurations, and different actuator sets or different actuator configurations may be implemented.

A discussion is now made regarding methods of controlling various catheter systems according to various embodiments. Although reference is made to catheter system **500** for ease of discussion, it is understood that the methods may be associated with other catheter devices or systems in other

122

embodiments. In some of these embodiments, a catheter system controlled by various ones of the described methods includes a catheter sheath (e.g., catheter sheath **512**) a proximal end (e.g., proximal end **512a**), a distal end (e.g., distal end **512b**), and a lumen (e.g., first lumen **512d**) extending between the proximal end of the catheter sheath and the distal end of the catheter sheath. The catheter system may further include a shaft (e.g., shaft **510**) comprising a proximal end (e.g., proximal end **510a**), a distal end (e.g., distal end **510b**), and an elongated portion (e.g., elongated portion **510c**) extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath prior to at least the elongated portion of the shaft. The catheter system may further include a manipulable portion (e.g., manipulable portion **502**) coupled to the shaft and located at least proximate the distal end of the shaft, the manipulable portion shaped for delivery through the lumen of the catheter sheath. The catheter system may further include a control element (e.g., control element **513**) physically coupled to the manipulable portion, the control element receivable in the lumen of the catheter sheath. In some embodiments, the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is shaped to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is shaped too large for delivery through the lumen of the catheter sheath, for example as described above with respect to manipulable portion **502**.

In some embodiments, each of various ones of the methods described in this disclosure is implemented under the guidance of a control system (e.g., control system **545** described later in this disclosure, or one or more components of system **100** or control system **322**, such as controller **324**). The control system may be a controller-based control system, a mechanical-based control system or a combination of the two. In some embodiments, each of various ones of the methods described in this disclosure may be implemented at least in part by manual input from an operator or user. It is understood that the methods described in this disclosure are not exhaustive and various aspects from different ones of the described methods may be combined to form at least one other method. Additionally, different sequences of steps or additional or alternate steps may be employed by at least some of the described methods. In some embodiments, each of various ones of the methods is employed to achieve a particular desired outcome of a portion of the catheter system (for example, a required control line tension adjustment that is the same or similar to that described above in this disclosure). In some embodiments, each of various ones of the methods is employed to achieve a particular deployment state of the catheter system operated in a medical treatment or diagnostic procedure.

A flow chart representing a method **900A** for controlling the catheter system according to various embodiments is provided in FIG. **9A**. In block **902** of method **900A**, at least a shape of the manipulable portion is modulated at least in a state where at least a part of the manipulable portion and a part of the control element extend outside the distal end of the catheter sheath. In some embodiments, a portion of shaft is located in a lumen of the sheath. The modulation of the manipulable portion may occur in a manner that is the same or similar to the modulation of the manipulable portion **502** in the sequence depicted in FIGS. **5I** and **5J** by way of non-limiting example. In various embodiments, the part of

123

the manipulable portion extending outside the distal end of the catheter sheath has a shape during or throughout the modulation that is too large to fit in the lumen of the catheter sheath. In block 904 of method 900A, the control element is manipulated to cause a length of the part of the control element extending outside the distal end of the catheter sheath to increase and subsequently decrease during or throughout the modulation of the manipulable portion. The manipulation of the control element may occur in a manner that is the same or similar to the manipulation of cable 513b in the sequence depicted in FIGS. 5H, 5I and 5J by way of non-limiting example.

A flow chart representing a method 900B for controlling the catheter system according to various embodiments is provided in FIG. 9B. In Block 912 of method 900B, the manipulable portion is transitioned at least partially between the expanded configuration and the delivery configuration. In block 914, a manipulation of the control element causes the control element to have a first amount of length located outside the distal end of the catheter sheath when a particular amount of the manipulable portion is located outside the distal end of the catheter sheath during a transition toward or to the expanded configuration. In block 916, a manipulation of the control element causes the control element to have a second amount of length located outside of the distal end of the catheter sheath, when the same particular amount of the manipulable portion is located outside the distal end of the catheter sheath during a transition toward or to the delivery configuration. In various embodiments, the second amount of length is different than the first amount of length. The transitioning of the manipulable portion at least partially between the expanded configuration and the delivery configuration may occur in a different manner in other embodiments. For example, an exploded view of block 912 is provided in FIG. 9C according to some embodiments. In block 912a the manipulable portion is transitioned toward or to the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath. In block 912b, the manipulable portion is transitioned toward or to the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath.

A flow chart representing a method 900C for controlling the catheter system according to various embodiments is provided in FIG. 9D. In block 922 of method 900C, the manipulable portion is transitioned at least partially between the expanded configuration and the delivery configuration. In block 924, a manipulation of the control element causes the control element to have a first amount of length located outside of the distal end of the catheter sheath when a particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward or to the expanded configuration. In block 926, a manipulation of the control element causes the control element to have a second amount of length located outside of the distal end of the catheter sheath when the same particular relative positioning exists between the catheter sheath and the shaft received in the lumen of the catheter sheath during the transition toward or to the delivery configuration. In various embodiments, the second amount of length is different than the first amount of length. In various embodiments, the particular relative positioning between the catheter sheath and the shaft received in the lumen of the catheter sheath is a relative longitudinal positioning.

A flow chart representing a method 900D for controlling the catheter system according to various embodiments is provided in FIG. 9E. In block 928 of method 900D, a first

124

relative movement is provided to cause a distance between a location on the part of the shaft received in the lumen of the catheter sheath and a location on the catheter sheath to decrease. In block 930 of method 900D, a second relative movement is provided to cause a distance between a location on the part of the shaft received in the lumen of the catheter sheath and a location on the catheter sheath to increase. Each of the first or second relative movements may be provided by a manipulation of the shaft, the catheter sheath or both the shaft and the catheter sheath. In block 932, in response to the first relative movement, a shape of at least a part of the manipulable portion extending outside the distal end of the catheter sheath is varied to, at least in part, cause the distal end of the manipulable portion to move along a first trajectory during the first relative movement. In block 934, in response to the second relative movement, a shape of at least a part of the manipulable portion extending outside the distal end of the catheter sheath is varied to, at least in part, cause the distal end of the manipulable portion to move along a second trajectory during the second relative movement. In various embodiments, the second trajectory is different than the first trajectory.

While some of the embodiments disclosed above are suitable for cardiac mapping, the same or similar embodiments may be used for mapping other bodily organs, for example gastric mapping, bladder mapping, arterial mapping and mapping of any bodily lumen, bodily chamber or bodily cavity into which the devices of the present invention may be introduced.

While some of the embodiments disclosed above are suitable for cardiac ablation, the same or similar embodiments may be used for ablating other bodily organs or any bodily lumen, bodily chamber or bodily cavity into which the devices of the present invention may be introduced.

Subsets or combinations of various embodiments described above can provide further embodiments.

These and other changes can be made to the invention in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the invention to the specific embodiments disclosed in the specification and the claims, but should be construed to include other catheter systems including all medical treatment catheter systems and medical diagnostic catheter systems in accordance with the claims. Accordingly, the invention is not limited by the disclosure, but instead its scope is to be determined entirely by the following claims.

What is claimed is:

1. A catheter system comprising:

a catheter sheath comprising a proximal end, a distal end, and a lumen extending within the catheter sheath between the proximal end of the catheter sheath and the distal end of the catheter sheath;

a shaft member comprising a shaft that includes a proximal end, a distal end, and an elongated portion extending between the proximal end of the shaft and the distal end of the shaft, at least part of the shaft sized for delivery through the lumen of the catheter sheath to a bodily cavity located in a body, and the distal end of the shaft arranged to be delivered through the lumen of the catheter sheath toward the bodily cavity prior to at least the elongated portion of the shaft;

a manipulable portion located at least proximate the distal end of the shaft, the manipulable portion sized for delivery through the lumen of the catheter sheath to the bodily cavity;

125

- a projection including a length and extending from a location at least proximate a first one of the proximal end of the catheter sheath and the proximal end of the shaft;
- a receiver provided at a location at least proximate a second one of the proximal end of the catheter sheath and the proximal end of the shaft, the projection and the receiver configured to matingly engage at least when the at least part of the shaft is received in the lumen of the catheter sheath; and
- an actuator system operatively coupled to the manipulable portion to transmit force to the manipulable portion, the actuator system responsive to varying amounts of the length of the projection being within the receiver by varying the force transmitted to the manipulable portion.
2. The catheter system of claim 1 wherein the projection extends beyond the first one of the proximal end of the catheter sheath and the proximal end of the shaft at least when the at least part of the shaft is received in the lumen of the catheter sheath.
3. The catheter system of claim 1 wherein the projection extends outwardly from the first one of the proximal end of the catheter sheath and the proximal end of the shaft toward one of the proximal end of the catheter sheath and the proximal end of the shaft other than the first one, at least when the at least part of the shaft is received in the lumen of the catheter sheath.
4. The catheter system of claim 1 wherein the manipulable portion is configured to not be inserted into the receiver when the manipulable portion is delivered through the lumen of the catheter sheath to the bodily cavity.
5. The catheter system of claim 1 wherein the length of the projection is a longitudinal length of the projection extending from the location at least proximate the first one of the proximal end of the catheter sheath and the proximal end of the shaft to an end of the projection, the end of the projection configured to be received first in the receiver, as compared to other parts of the projection, when the projection is inserted into the receiver.
6. The catheter system of claim 5 wherein the shaft comprises a longitudinal length extending between the proximal and distal ends of the shaft, and wherein the longitudinal length of the shaft is different than the longitudinal length of the projection.
7. The catheter system of claim 5 wherein the shaft comprises a longitudinal length extending between the proximal and distal ends of the shaft, and wherein the longitudinal length of the shaft is greater than the longitudinal length of the projection.
8. The catheter system of claim 5 wherein the shaft comprises a longitudinal length extending between the proximal and distal ends of the shaft, and wherein a first particular amount of the longitudinal length of the projection is located in the receiver when a second particular amount of the longitudinal length of the shaft is located inside the lumen of the catheter sheath, the first particular amount of the longitudinal length of the projection being less than second particular amount of the longitudinal length of the shaft.
9. The catheter system of claim 1 wherein the first one of the proximal end of the catheter sheath and the proximal end of the shaft is a same one as the second one of the proximal end of the catheter sheath and the proximal end of the shaft.

126

10. The catheter system of claim 1 wherein the first one of the proximal end of the catheter sheath and the proximal end of the shaft is different than the second one of the proximal end of the catheter sheath and the proximal end of the shaft.
11. The catheter system of claim 1 wherein the second one of the proximal end of the catheter sheath and the proximal end of the shaft is the proximal end of the shaft.
12. The catheter system of claim 11 wherein the first one of the proximal end of the catheter sheath and the proximal end of the shaft is the proximal end of the catheter sheath.
13. The catheter system of claim 1 wherein the shaft member further comprises a housing physically coupled to the shaft at a location at least proximate the second one of the proximal end of the catheter sheath and the proximal end of the shaft, and wherein the receiver is located, at least in part, in the housing.
14. The catheter system of claim 13 wherein the actuator system is located, at least in part, in the housing.
15. The catheter system of claim 1 wherein the receiver comprises an internal receiving mechanism sized to matingly receive at least a portion of the projection, and wherein the actuator system is responsive to a movement of the internal receiving mechanism within the receiver caused by a change in an amount of the length of the projection within the receiver by varying the force transmitted to the manipulable portion.
16. The catheter system of claim 15 wherein the internal receiving mechanism comprises a coupler that physically couples the internal receiving mechanism to at least the portion of the projection when at least the portion of the projection is matingly received in the internal receiving mechanism, and wherein, when at least the portion of the projection is physically coupled to the internal receiving mechanism, at least the coupler of the internal receiving mechanism is configured to move during each of a first relative movement between the projection and the receiver that increases the amount of the length of the projection within the receiver, and a second relative movement between the projection and the receiver that decreases the amount of the length of the projection within the receiver.
17. The catheter system of claim 16 wherein the coupler captively couples the internal receiving mechanism to at least the portion of the projection when at least the portion of the projection is matingly received in the internal receiving mechanism.
18. The catheter system of claim 16 wherein the coupler is configured to physically couple the internal receiving mechanism to at least the portion of the projection when a first relative positioning between the projection and the receiver is established, and wherein the coupler is configured to physically de-couple the internal receiving mechanism from the projection when a second relative positioning between the projection and the receiver is established, the second relative positioning being different than the first relative positioning.
19. The catheter system of claim 1, further comprising a control cable that operatively couples the actuator system to the manipulable portion, the control cable receivable in the lumen of the catheter sheath, wherein the actuator system is configured to meter the control cable to vary an amount of the control cable that

127

extends outwardly from the distal end of the catheter sheath when the at least part of the shaft is received in the lumen of the catheter sheath, and

wherein the actuator system is responsive to varying amounts of the length of the projection being within the receiver by varying a rate at which the control cable is metered.

20. The catheter system of claim **1**, further comprising a control cable that operatively couples the actuator system to the manipulable portion, the control cable receivable in the lumen of the catheter sheath,

wherein the actuator system is configured to meter the control cable to vary an amount of the control cable that extends outwardly from the distal end of the catheter sheath when the at least part of the shaft is received in the lumen of the catheter sheath, and

wherein the actuator system is responsive to a rate of change in an amount of the length of the projection being within the receiver by varying a rate at which the control cable is metered.

21. The catheter system of claim **19**

wherein the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath,

wherein the actuator system is operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath, and

wherein the actuator system is operatively coupled to the control cable to cause, when a particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the control cable to be metered with a first rate, and

wherein the actuator system is operatively coupled to the control cable to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the control cable to be metered with a second rate different than the first rate.

22. The catheter system of claim **1**

wherein the manipulable portion is selectively moveable between a delivery configuration in which the manipulable portion is sized to be delivered through the lumen of the catheter sheath and an expanded configuration in which the manipulable portion is sized too large for delivery through the lumen of the catheter sheath,

wherein the catheter system further comprises a control element that operatively couples the actuator system to the manipulable portion, the control element receivable in the lumen of the catheter sheath,

wherein the actuator system is operatively coupled to the manipulable portion to transition the manipulable portion, at least in part, toward the expanded configuration as the manipulable portion is advanced out of the distal end of the catheter sheath, and to transition, at least in part, the manipulable portion toward the delivery configuration as the manipulable portion is retracted into the distal end of the catheter sheath,

128

wherein the actuator system is operatively coupled to the control element to cause, when a particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the control element to have a first amount of length located outside of the distal end of the catheter sheath, and

the actuator system is operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the control element to have a second amount of length located outside of the distal end of the catheter sheath, the first amount of length different than the second amount of length.

23. The catheter system of claim **22** wherein the control element comprises a sleeve and a cable received in a lumen of the sleeve, each of the sleeve and the cable received in a lumen of the shaft.

24. The catheter system of claim **22**

wherein the control element comprises a sleeve and a cable located, at least in part, in a lumen of the sleeve, wherein the actuator system is operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the expanded configuration, the cable to have a third amount of length located outside an end of the sleeve, and

wherein the actuator system is operatively coupled to the control element to cause, when the particular amount of the length of the projection is received in the receiver during the transition toward the delivery configuration, the cable to have a fourth amount of length located outside the end of the sleeve, the fourth amount of length different than the third amount of length.

25. The catheter system of claim **1** wherein the manipulable portion comprises a set of one or more transducers.

26. The catheter system of claim **1** wherein the catheter sheath, the at least part of the shaft receivable in the lumen of the catheter sheath, or each of the catheter sheath and the at least part of the shaft receivable in the lumen of the catheter sheath comprises a bendable portion sufficiently bendable for delivery to the bodily cavity.

27. The catheter system of claim **1** wherein the projection and the receiver are configured to matingly engage at least when a first amount of the shaft is received in the lumen of the catheter sheath, and the projection and the receiver are configured to not matingly engage at least when a second amount of the part of the shaft is received in the lumen of the catheter sheath.

28. The catheter system of claim **27** wherein the first amount of the part of the shaft is different than the second amount of the shaft.

29. The catheter system of claim **28**

wherein the shaft comprises a longitudinal length extending between the proximal and distal ends of the shaft, and

wherein each of the first amount and the second amount of the part of the shaft are an amount of the longitudinal length of the shaft.

30. The catheter system of claim **1** wherein the projection and the receiver are configured to matingly engage at least when the shaft is not received in the lumen of the catheter sheath.

31. The catheter system of claim **1** wherein the projection and the receiver form part of a plunger assembly located on one of the shaft and the catheter sheath.

129

32. The catheter system of claim 1

wherein the manipulable portion comprises a distal end,
the distal end of the manipulable portion arranged to be
advanced outwardly first from the distal end of the
catheter sheath, as compared to other parts of the
manipulable portion, and

wherein the actuator system is configured to vary the
force transmitted to the manipulable portion while the
distal end of manipulable portion advances outwardly
from the distal end of the catheter sheath along an
arcuate path.

33. The catheter system of claim 1

wherein the manipulable portion comprises a distal end,
the distal end of the manipulable portion arranged to be
advanced outwardly first from the distal end of the
catheter sheath, as compared to other parts of the
manipulable portion, and

wherein the actuator system is configured to vary the
force transmitted to the manipulable portion while the
distal end of manipulable portion advances outwardly
from the distal end of the catheter sheath along a coiled
path.

34. The catheter system of claim 1, further comprising a
control cable that operatively couples the actuator system to
the manipulable portion, the control cable receivable in a
lumen of the shaft,

wherein the actuator system is configured to meter the
control cable, and

wherein the actuator system is responsive to varying
amounts of the length of the projection being within the
receiver by varying a rate at which the control cable is
metered.

35. The catheter system of claim 1 wherein the projection
extends in a particular direction at the location at least
proximate the first one of the proximal end of the catheter
sheath and the proximal end of the shaft that is substantially
parallel to a particular direction that a particular one of the
catheter sheath and the shaft that comprises the first one of

130

the proximal end of the catheter sheath and the proximal end
of the shaft extends at the location at least proximate the first
one of the proximal end of the catheter sheath and the
proximal end of the shaft.

36. A method of operating a catheter system, the catheter
system comprising a catheter sheath, a shaft member, a
manipulable portion, a projection, a receiver, and an actuator
system, the catheter sheath comprising a proximal end, a
distal end, and a lumen extending within the catheter sheath
between the proximal end of the catheter sheath and the
distal end of the catheter sheath, the shaft member compris-
ing a shaft that includes a proximal end, a distal end, and an
elongated portion extending between the proximal end of the
shaft and the distal end of the shaft, at least part of the shaft
sized for delivery through the lumen of the catheter sheath
to a bodily cavity located in a body, and the distal end of the
shaft arranged to be delivered through the lumen of the
catheter sheath toward the bodily cavity prior to at least the
elongated portion of the shaft, the manipulable portion
located at least proximate the distal end of the shaft, the
manipulable portion sized for delivery through the lumen of
the catheter sheath to the bodily cavity, the projection
including a length and extending from a location at least
proximate a first one of the proximal end of the catheter
sheath and the proximal end of the shaft, the receiver
provided at a location at least proximate a second one of the
proximal end of the catheter sheath and the proximal end of
the shaft, the actuator system operatively coupled to the
manipulable portion to transmit force to the manipulable
portion, and the method comprising:

 matingly engaging the projection and the receiver at least
 when the at least part of the shaft is received in the
 lumen of the catheter sheath; and

 varying an amount of the length of the projection within
 the receiver to cause the actuator system to vary the
 force transmitted to the manipulable portion.

* * * * *